

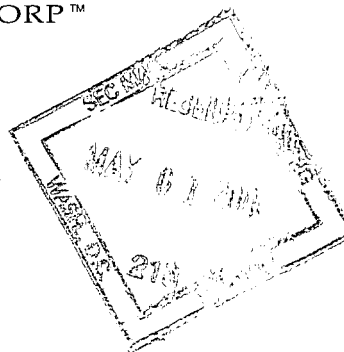


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Developments in 2005

- ***Advancis began its pivotal Amoxicillin PULSYS Phase III trial in adolescents and adults.***

In November 2005, we began enrolling patients into our redesigned Phase III trial for our Amoxicillin PULSYS product candidate in adults and adolescents with pharyngitis/tonsillitis due to Group A strep infections (commonly referred to as strep throat). Following extensive analysis of data from our prior Amoxicillin PULSYS clinical trials, we decided to extend the length of treatment for our product in the redesigned Phase III trial in adults and adolescents from seven days to 10 days.

- ***Advancis decided to retain its Keflex® brand and increase its Keflex product offerings.***

In January 2006, we announced that the potential sale of the U.S. rights to the Keflex® brand of cephalexin had not been completed by December 31, 2005, and that we had decided to retain the assets. We had previously entered into an agreement-in-principle in August 2005 which contemplated the sale of our Keflex rights to a private company. We are now pursuing approval and commercial launch of new Keflex line extension products and are seeking partners to assist in the marketing and sale of Keflex products. We filed a supplemental NDA for the new products with the FDA on December 20, 2005, and the supplement was accepted for filing by the FDA in February 2006.

- ***Advancis took steps to significantly reduce its level of spending.***

During the third quarter of 2005, we undertook actions to lower expenses by reducing our employee workforce by approximately one third and eliminating all nonessential temporary personnel. Overall reduction in staff was approximately 38 percent. We identified positions for reduction across all functional business areas and managerial levels, resulting in the elimination of 33 jobs. Following the reductions in these positions, the Company had a total of 54 employees.

- ***Advancis received results from its pediatric and adult Amoxicillin PULSYS Phase III trials.***

The Company's two Amoxicillin PULSYS Phase III clinical trials for the treatment of adolescents/adults and children with strep throat failed to achieve their desired microbiological and clinical endpoints. In June 2005, we reported that our once-daily adolescent/adult Amoxicillin PULSYS therapy achieved a bacteriological rate of 76.6 percent and in July 2005 reported that our pediatric therapy achieved a 65.3 percent eradication rate. Both trials failed to achieve eradication rates that were statistically non-inferior to the four-times-a-day comparator therapy and also failed to reach the 85 percent eradication rate necessary for FDA approval as a first-line therapy for strep throat.

- ***Advancis raised \$27 million through a private placement of common equity.***

In April 2005, we entered into definitive purchase agreements for the private placement of 6.8 million shares of common stock, raising \$27.25 million in gross proceeds. The newly issued shares were priced at \$3.98, equal to the closing price the day prior to the transaction. Investors in the private placement received five-year warrants to purchase approximately 2.4 million shares of common stock at an exercise price of \$4.78 per share. The financing syndicate included Omega Fund, HealthCare Ventures, and Rho Ventures with an aggregate investment of approximately 5.8 million shares. In addition, several new institutional investors participated in the financing.

- ***Advancis secured commercial supply arrangements for Keflex® and Amoxicillin PULSYS.***

We announced in April 2005 that we entered into agreements under which Stada Production Ireland Limited, a subsidiary of STADA Group, will provide Advancis with commercial supply of our Amoxicillin PULSYS products, pending the successful completion of our clinical trial and regulatory approval. Stada has capacity in place to provide for current projected needs for an initial commercial phase, with additional capacity for growth. In late 2004, we also entered into a commercial supply agreement with Ceph International Corporation, a wholly owned subsidiary of Patheon Inc. With the agreement, we secured a long-term supply for our Keflex® (cephalexin capsules, USP) brand of products.

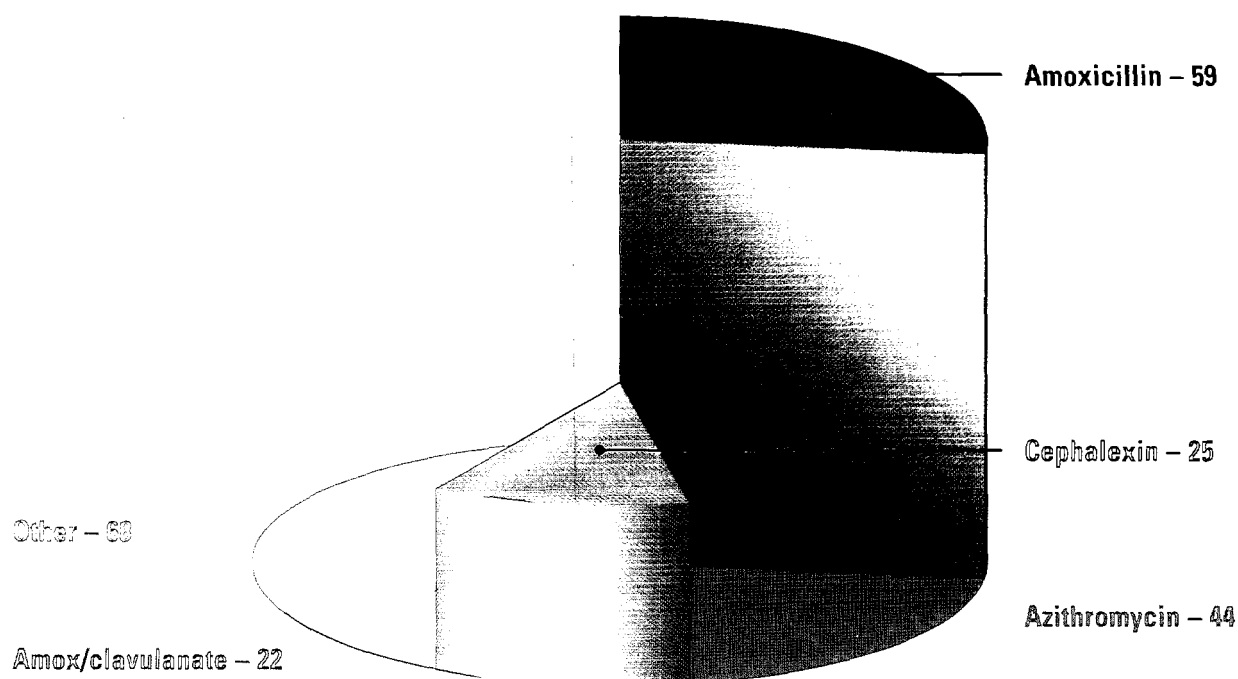
Corporate Profile

Advancis Pharmaceutical Corporation is a pharmaceutical company focused on developing and commercializing pulsatile drug products that fulfill unmet medical needs in the treatment of infectious diseases. We are developing a portfolio of drugs based on our novel biological finding that bacteria exposed to antibiotics in front-loaded, staccato bursts, or pulses, are killed more efficiently than those exposed to standard antibiotic treatment regimens. Based on this finding, we have developed a proprietary, once-a-day pulsatile delivery technology called PULSYS™. Our lead product, Amoxicillin PULSYS, is in a Phase III pivotal trial during the first half of 2006, and if successful, could be launched by as early as 2007.

PULSYS Product Pipeline Targets the Highest Volume Antibiotics

Advancis' product candidates pursue two of the top three most-prescribed antibiotics*

Top Ten Oral Antibiotics by Volume* (Millions of prescriptions written in 2005)



Advancis' PULSYS product candidates are designed to offer significant competitive advantages by delivering once-daily dosing, less total drug quantity, and possible shorter courses of therapy

PULSYS PRODUCT CANDIDATES

PULSYS Product Candidate	Key Indication(s)	Standard Therapy	Targeted PULSYS Added Value	Program Status
Amoxicillin - Adult	Pharyngitis/tonsillitis	10-14 days, two or three times daily	10 days, once-daily, lower dose	Phase III
Keflex (cephalexin) - Adult	Skin and skin structure	7-14 days, two to four times daily	Once-daily, lower dose	Phase I
Pediatric Pharyngitis Program	Pharyngitis/tonsillitis	10-14 days, two or three times daily	10 days, once-daily, lower dose, improved convenience	Phase I

*Based on IMS Health, National Prescription Audit 2005.



R. Gordon Douglas, M.D.
Chairman of the Board



Edward M. Rudnic, Ph.D.
President & CEO

Dear Fellow Shareholders:

When we founded Advancis in 2000, we set out to develop and commercialize anti-infective products based on our PULSYS™ technology. Later in 2006 – only six years after founding the company – we expect to have results from a Phase III study for our lead product, Amoxicillin PULSYS. If the results of the Amoxicillin PULSYS trial are positive, Advancis will file an application with the U.S. Food and Drug Administration (FDA) for approval of the first and only once-daily amoxicillin product in the U.S. We look forward to completing the study and sharing the results from this trial later in the third quarter of 2006.

Of course in 2005, Advancis was reminded of how arduous and frustrating drug development can be, as two clinical trials involving Amoxicillin PULSYS failed to meet their required endpoints. Despite the negative studies, we are proud of our employees and their hard work in 2005. While the trial results did not support a regulatory filing, we gained important knowledge about Amoxicillin PULSYS, which has been applied to the design of our new clinical trial. We believe the lessons learned will help improve our chances of success in 2006. The ongoing study was initiated in fall of 2005 and will be one of the largest clinical trials assessing the efficacy of amoxicillin in the treatment of pharyngitis ever undertaken. We expect to enroll more than 600 patients in the study and if we meet the endpoints in this study, we believe the study will form the basis for a New Drug Application (NDA) supporting approval of Amoxicillin PULSYS in the U.S.

Also in 2005, we were reminded of the importance our technology may eventually play in the treatment of infectious disease. Concerns regarding antibiotic resistance, the dearth of new therapies in development, and the fear of flu epidemics and other infectious diseases continue to be high profile subjects among public health policy makers, the U.S. public, and throughout the world. Advancis is one of a dwindling number of companies actively developing new antibiotics for the market. The work that we do here at Advancis may lead to enhancements

of existing antibiotics that extend their utility for another generation. Even more importantly, some of our earliest stage combination products may prove to be potent therapeutics against resistant bacteria and result in breakthrough treatments for an area of high unmet medical need.

Our business is focused on the development of antibiotics that can be utilized to successfully treat community-acquired bacterial infections. Our lead candidate, Amoxicillin PULSYS, is based on a drug that continues to play a critical role in the treatment of several upper respiratory tract infections and is the number-one prescribed type of antibiotic in the United States. Our Keflex brand of cephalexin is the flagship brand of that antibiotic, the third most prescribed antibiotic in the United States, and the number-one prescribed antibiotic for treatment of uncomplicated skin infections. We believe our efforts to develop PULSYS versions of these off-patent compounds could result in their utility as front-line antibiotics continuing for another generation as our patented technology addresses a fundamental weakness both drugs share: inconvenience. Inconvenience can lead to missed doses, which may result in treatment failures and the development of antibiotic resistance. We believe addressing inconvenience could markedly improve these drugs' utility going forward by leading to better compliance and more successful treatment outcomes.

As we look forward into 2006, we have many reasons for optimism, including reliable revenue from sales of our existing products, new products that we hope to introduce in the second half of the year, and the anticipated results of our redesigned clinical trial for Amoxicillin PULSYS.

Our main areas of focus in 2006 are:

- Completion of our Amoxicillin PULSYS Phase III trial in adolescents and adults with strep throat;
- Launch of new Keflex products, for which we filed a supplemental New Drug Application (NDA) in December of 2005;
- Assuming positive results from our Amoxicillin PULSYS clinical trial, beginning development of additional PULSYS antibiotic candidates; and
- Providing greater financial security for Advancis by increasing our cash reserves and/or reducing our need for additional financing.

Amoxicillin PULSYS

Amoxicillin PULSYS is currently under evaluation in a Phase III clinical trial for adolescents and adults with pharyngitis/tonsillitis – commonly referred to as strep throat. Patient enrollment is proceeding as expected and we expect to announce top-line results from the trial in the third quarter of 2006. Our pulsatile amoxicillin product candidate is being dosed at 775 mg once-daily for 10 days, which is an increase of three days of therapy over our prior trials. We believe this additional 42 percent of drug delivered and extended length of therapy will provide the added benefit needed to produce a successful outcome.

Through a series of meetings with the FDA, we have concluded that approval from our current trial will be determined based on demonstrating statistical non-inferiority of our once-daily therapy when compared to a standard four-times-

a-day penicillin therapy. In addition, at least 85 percent of Amoxicillin PULSYS patients in our trial must experience complete eradication of the bacteria responsible for their strep throat infection. In last year's unsuccessful Phase III trial in adolescents and adults, we achieved a bacterial eradication rate of 76.7 percent for seven days of therapy, compared to 88.5 percent for the comparator therapy given for ten days.

In the U.S., the most common prescription for pharyngitis is 500mg of amoxicillin three times daily for 10 days. If our trials are successful and the drug is approved for marketing, we believe the added convenience of Amoxicillin PULSYS would have great market appeal. The current size of the retail amoxicillin market in the U.S. is estimated to be approximately \$600 million per year with more than 59 million prescriptions.

Keflex® Product Sales

We expect 2006 to be a pivotal year for Keflex as we anticipate approval for line extensions filed with FDA in 2005. The line extensions, if approved, would have market exclusivity for some period of time, allowing us to grow the brand considerably above the \$4.8 million in sales recorded in 2005. We expect FDA to take action on the new products application in May 2006 and, if it is approved, expect to launch the products in the second half of the year.

Of course, we also remain optimistic about our prospects for developing a once-daily version of Keflex based on our PULSYS technology. We initiated Phase I clinical trials in late 2005 for this candidate and hope to advance into Phase II clinical development in the first half of 2007. In 2005, Keflex and generic cephalexin had retail sales of more than \$500 million on approximately 25 million prescriptions – with very little overlap in usage with amoxicillin.

Our PULSYS Product Pipeline

Should we achieve a successful outcome for our Amoxicillin PULSYS clinical trial, we expect to begin development of additional antibiotic product candidates utilizing our PULSYS technology. In addition to continuing development of a PULSYS version of Keflex, we are eager to continue working towards PULSYS products addressing a variety of common infections including: sinusitis, bronchitis, ear infections and urinary tract infections. We are also very encouraged about the prospect of developing a PULSYS combination product that may be able to address the growing threat of methicillin-resistant *Staphylococcus aureus* (MRSA), bacteria that are responsible for an increasing number of life-threatening infections.

Our Financial Position

We ended 2005 with \$29 million of cash and marketable securities, which was approximately the same amount as of the end of 2004, due primarily to the completion of our \$27.25 million private offering of common stock in April 2005. We continue to have very little debt, and reported a total of only \$1.6 million of debt at year-end.

Additionally, we have been able to conduct our business in a relatively cost-efficient manner. During 2005, we used approximately \$25 million for our operations and \$2 million

on the purchase of property and equipment. In August, we undertook steps to reduce our expenses, including foregoing discretionary expenditures, reducing our workforce by about one-third and channeling our resources into our two most promising product candidates: Amoxicillin PULSYS and Keflex.

If approved for marketing, we believe our new Keflex line extension products could serve as a potential source of incremental capital to offset the need to draw on existing corporate resources or to raise additional capital through future equity financings. However, even without additional capital, we believe that our current liquidity, together with expected sales from existing Keflex products during the year, will support our anticipated future operations into the first quarter of 2007.

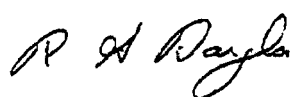
The Year Ahead

We anticipate two pivotal events for Advancis in 2006 – receiving a decision from the FDA on our new Keflex products in May, and receiving top-line results from our Amoxicillin PULSYS clinical trial in the third quarter of 2006. Should we receive approval on the new Keflex products, we expect to finalize the details of our commercialization strategy supporting the products and to launch sales as early as the second half of 2006. If our Amoxicillin PULSYS Phase III trial is successful, we anticipate responding quickly, filing our New Drug Application around year-end and possibly launching the product as early as late 2007. We are very excited about the potential to have the first and only once-daily amoxicillin product with marketing approval for pharyngitis/tonsillitis in the U.S.

Further, if we are successful in gaining approvals for our new Keflex products and for Amoxicillin PULSYS, we are optimistic about our ability to continue development of a once-daily PULSYS version of Keflex, as well as our ability to advance our pipeline of other promising product candidates into clinical trials. We are working to develop a portfolio of once-a-day PULSYS antibiotic products that target respiratory tract and skin infections and cover the majority of antibiotics-related diagnoses.

We look forward to 2006 with optimism, and are hopeful that we will be able to build on our upcoming pivotal events and produce positive milestones that will drive enhanced value for our shareholders, employees and other constituents. We are working diligently to realize the turnaround that we believe will establish Advancis among the leading anti-infective drug discovery organizations. Our entire team at Advancis is aligned with the interests of shareholders for the future success of our company. We are committed to driving this process forward and are hopeful that our hard work will be rewarded in increased value for our shareholders beginning in 2006.

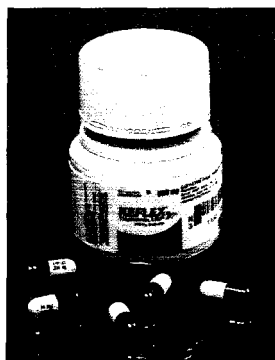
Sincerely,



R. Gordon Douglas, M.D.
Chairman of the Board



Edward M. Rudnic, Ph.D.
President & CEO



Enduring Efficacy

Keflex, which works by inhibiting cell-wall synthesis of susceptible organisms, has demonstrated a broad bactericidal spectrum. Keflex is approved for the following:

- Skin and skin structure infections
- Respiratory tract infections
- Otitis media
- Bone infections
- Genitourinary tract infections

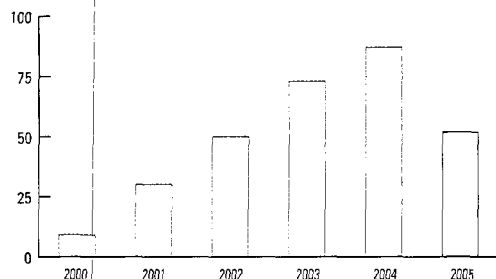
Established Safety

- Keflex is well-tolerated by patients
- Keflex offers consistent performance regardless of age
- Keflex has low potential for drug-drug interaction

Keflex Products	Key Indication(s)	Status	Marketing Rights
Keflex Capsules – 250 mg and 500 mg	Skin and skin structure infections; upper respiratory tract infections	FDA-approved	U.S. & Puerto Rico rights
Keflex Powder for Oral Suspension	Skin and skin structure infections; upper respiratory tract infections	FDA-approved	U.S. & Puerto Rico rights
Keflex Line Extension products ¹	Skin and skin structure infections; upper respiratory tract infections	Pending FDA-approval ¹	U.S. & Puerto Rico rights

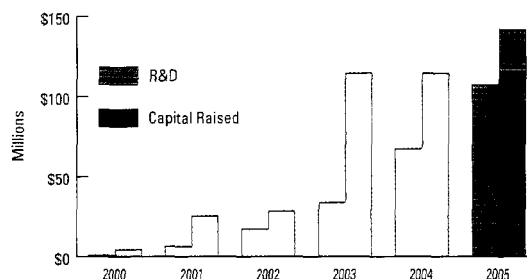
¹ On December 20, 2005, we submitted a supplemental NDA (sNDA) to the U.S. Food & Drug Administration requesting approval of our new Keflex products.

Employees



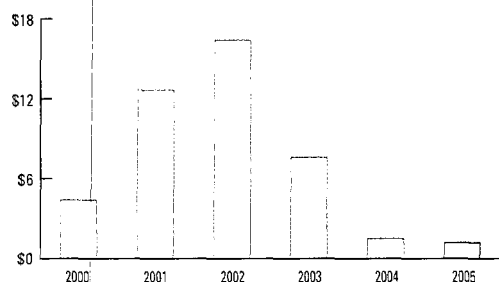
- Advancis had a total of 52 at the end of 2005
 - 30 employees perform scientific and research activities
 - 15 employees hold advanced degrees

Cumulative Capital Raised and R&D Dollars Spent



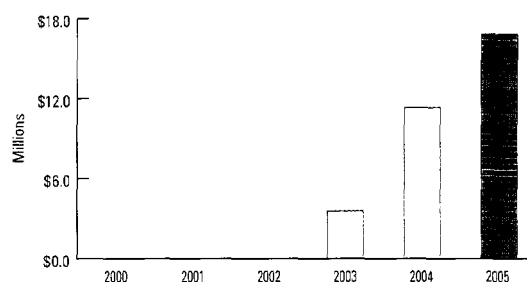
- Advancis has raised more than \$140 million in capital since 2000
- Advancis has invested a total of \$107.25 million in its research and development programs for its product candidates since 2000

Net Loss Per Share



- Advancis has reduced net loss per share to \$1.20 in 2005

Revenue



- Advancis had revenue of \$16.8 million in 2005 – composed of:
 - \$4.8 million of net Keflex product sales
 - \$4.0 million of contract revenue from collaborations
 - \$8.0 million of reimbursed development costs – Amoxicillin PULSYS collaboration

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

- ☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2005

or

- ☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 000-50414

ADVANCIS PHARMACEUTICAL CORPORATION

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

20425 Seneca Meadows Parkway

Germantown, Maryland

(Address of principal executive offices)

52-2208264

(I.R.S. employer
identification number)

20876

(Zip Code)

(301) 944-6600

(Registrant's telephone number, including area code)

None

(Former name, former address and former fiscal year — if changed since last report)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, par value \$0.01 per share**

Indicate by check mark if the registrant is a well-known, seasoned issuer, as defined by Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Exchange Act Rule 12b-2). (Check one):

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-accelerated Filer ☒

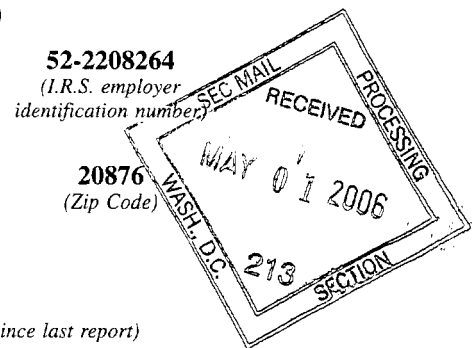
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes ☐ No ☒

As of June 30, 2005, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$19,866,404.

As of March 10, 2006, 30,253,391 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Advancis Pharmaceutical Corporation's Notice of Annual Stockholder's Meeting and Proxy Statement, to be filed within 120 days after the end of the registrant's fiscal year, are incorporated by reference into Part III of this Annual Report.



ADVANCIS PHARMACEUTICAL CORPORATION

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the primary therapy. As a result, we believe there is a strong demand for new treatments that are more potent, more effective against resistant strains and that cause fewer side effects.

Difficulties in developing new classes of anti-infective compounds. We believe that the growing problem of resistance and other limitations of currently available antibiotics are not being adequately addressed. Moreover, many of the large pharmaceutical companies have reduced research and development efforts in this sector and others have stopped producing anti-infective products.

Limitations of standard treatment regimens. In addition to the increased incidence of antibiotic resistant bacteria, we believe that standard antibiotic treatment regimens have several other limitations, including multiple daily dosage requirements, lengthy treatment periods, limited effectiveness and severe side effects, all of which decrease patient compliance and ultimately, therapeutic efficacy.

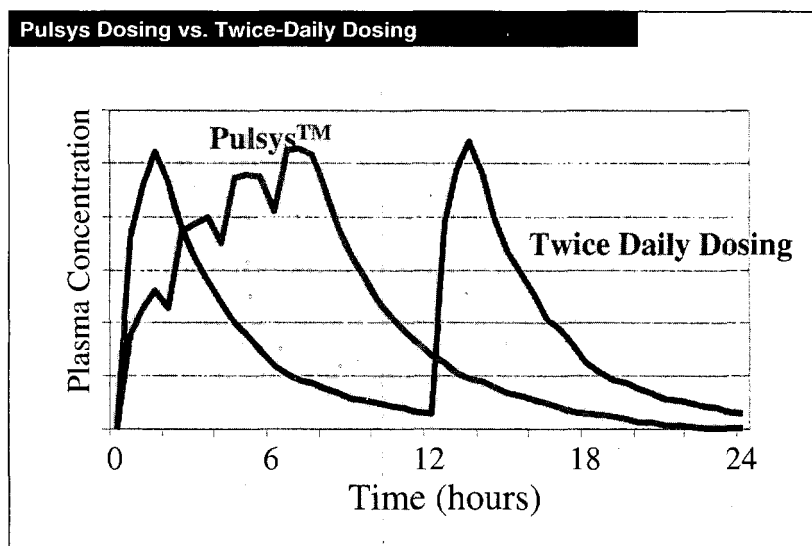
Our Proprietary PULSYS Technology

The significant unmet needs in the anti-infective market prompted our founders to search for a more efficient method to attack bacteria. In a series of seminal laboratory experiments, we observed that antibiotics such as amoxicillin are more effective in killing bacteria when delivered in three to five discrete pulses of drug within the initial six to eight hours of a dosing interval. To take advantage of these experimental findings, we created a proprietary, once-a-day oral drug delivery technology called PULSYS™. PULSYS is designed to sequentially release specific portions of the drug dose, yielding a pulsatile pattern of antibiotic release. We believe that our novel finding, as implemented through our PULSYS technology, will potentially enable therapeutic advantages including:

- Improved bactericidal activity, or bacteria killing efficiency.
- Once-daily dosing and shorter length of treatment resulting in increased patient convenience and compliance.
- Lower overall drug dose with a possibly reduced side effect profile.
- Decreased emergence of antibiotic resistant bacteria.

Our approach to improving antibiotic effectiveness represents a departure from traditional methods, which have focused on increasing drug dosages and searching for new classes of drugs. Our pulsatile dosing approach attempts to increase antibiotic effectiveness by better exploiting vulnerabilities in the growth cycle and natural defense mechanisms of bacteria.

The graph below conceptually illustrates drug concentration profiles in a patient's bloodstream over a 24-hour period comparing drugs administered through our PULSYS system with standard twice daily dosing. The standard dosing regimen reflects the administration of an immediate release tablet at the start of a day, followed by an additional immediate release tablet 12 hours later. The PULSYS profile reflects the administration of a single dose designed to release the drug in four front-loaded pulses, with no additional doses administered for the balance of the day.



PULSYS is a proprietary method of administering a pharmaceutical agent such that the active ingredient is given in a front loaded, sequential pulse fashion. PULSYS can be realized or practiced by administering a solid oral dosage form that may contain multiple units, for example pellets, minitables, etc. with varying release profiles that are combined in a proportion to produce optimum medication levels during the first few hours after dosing. PULSYS can also be realized as other dosage forms such as topicals, transdermals, insertables, etc. We anticipate that our pulsatile drug products could each provide for once-a-day dosing. We strive to utilize commonly-used inactive ingredients and common manufacturing processes when making PULSYS or any other type of anti-infective product. We are exploring the pulsatile administration of anti-infective agents in forms other than solid oral dosage forms.

PULSYS drug product candidates are evaluated using our proprietary design strategy. We are currently focusing on antibiotics, but also have proprietary positions in the antiviral, antifungal and antineoplastics fields. This approach combines computer simulations with microbiology and other laboratory experiments to analyze the physical, chemical, biological and microbiological properties of each specific antibiotic in order to optimize selection and design of pulsatile drug candidates. This analysis includes an evaluation of the physicochemical properties and metabolism profiles of antibiotics as a function of position in the gastro-intestinal tract. We attempt to optimize overall antibiotic bioavailability by adjusting the timing and composition of pulses. By examining the bioavailability of antibiotics prior to the selection of PULSYS candidates, we believe that we will increase the likelihood of successful product development.

Our Strategy

We expect to use our novel finding and related proprietary technology to develop and commercialize more efficient, effective and convenient pharmaceutical products, with an initial focus on antibiotics. To achieve this objective, we have adopted the following product development and commercialization strategies:

Commercialize products with multiple advantages. We plan to develop PULSYS products that have multiple therapeutic advantages over currently available antibiotics, which may include once-daily dosing, lower doses, and in some cases, shorter treatment periods. We believe that these advantages will be further reflected with at least some of our PULSYS products in fewer dose-related side effects, reduced incidence of resistance and improved efficacy.

Focus initially on existing antibiotics. We anticipate reducing development risk and expense and decreasing time to market for our drug candidates by focusing on improved versions of approved and marketed drugs, either delivered alone or in combination with other drugs. The additional benefits of developing improved formulations of existing and approved antibiotics include reasonable and predictable production costs and higher probability of market acceptance due to the use of well-known antibiotics. In addition, since these existing products have already been proven to be safe and effective, we anticipate being able to rely on existing approvals and existing safety and efficacy data, which would allow us to reduce the amount of new data that we will need to generate in order to support FDA approval of our products.

Focus on first-line, broad-spectrum antibiotics for community infections. We are pursuing a product development strategy focused primarily on first-line, broad spectrum antibiotics for community infections. Our pulsatile antibiotic products are expected to target upper respiratory tract infections and skin and skin structure infections in particular. The target indications for our current product candidates cover some of the top antibiotics-related diagnoses and are intended to compete against the top most-prescribed antibiotics. We believe products utilizing our front-loaded, pulsed dosing approach will support once-daily dosing where two-to-four times daily dosing is the norm, with a concomitant reduction in dose and treatment duration (in some cases) compared to current traditional therapies.

Develop sales and marketing functions across multiple products. We intend to build over time a pharmaceutical company which may include discovery, development, manufacturing, distribution, sales, and marketing capabilities. We believe that this commercialization strategy will allow us to fully maximize the value of our PULSYS product assets and retain significant control over our development and commercial activities. In support of the introduction of our first proprietary product, Amoxicillin PULSYS, we are considering several sales and marketing strategies, including the establishment of our own sales and marketing infrastructure. We believe that a significant proportion of prescriptions for first-line, broad-spectrum antibiotics is written by a relatively small number of high-volume prescribers who can be reached by a community-based sales force. Over time, we intend to expand our sales and marketing capabilities to provide even greater support of our target audiences. We also may enter into agreements with other pharmaceutical companies to exploit our partners' sales and marketing capabilities in order to optimally market our products.

Multi-level patent strategy. We have implemented a multi-level patent strategy in order to protect our anticipated pulsatile drug products. The first level is composed of "umbrella" patents and patent applications to protect the PULSYS administration of general classes of anti-infective drugs, such as antibiotics, antivirals, antifungals and antineoplastics. The second level is composed of "sub-umbrella" patents and patent applications, protecting the PULSYS administration of subclasses of drugs, such as beta-lactam antibiotics with enzyme inhibitors. The third level includes patents and applications for specific anti-infective agents. We intend to continue to use and enhance this strategy in order to protect our intellectual property. We currently own 19 issued U.S. patents and 23 U.S. patent applications. Our issued patents cover certain compositions and methods for using pulsatile dosing. We also own 56 foreign-filed patent applications, which correspond to our U.S. patents and applications. We also own 3 International (PCT) patent applications, each of which International (PCT) patent applications we anticipate converting into several individually foreign-filed patent applications to further correspond to our U.S. patents and applications.

License or acquire antibiotic products. We continue to explore pulsatile formulations for a wide range of other antibiotics and antibiotic combinations and we may in-license or acquire antibiotic products that we believe can be improved with our novel pulsatile dosing approach.

Our Marketed Products

Keflex

On June 30, 2004, we acquired the U.S. rights to the Keflex brand of cephalexin from Eli Lilly and Company. The purchase price was \$11.2 million, including transaction costs, which was paid in cash from our working capital. The asset purchase includes the exclusive rights to manufacture, sell and market Keflex in the United States (including Puerto Rico). We also acquired Keflex trademarks, technology and new drug applications (NDAs) supporting the approval of Keflex capsules and oral suspension. In addition, on December 9, 2004, we announced

that we entered into a commercial supply agreement with Ceph International Corporation, a wholly owned subsidiary of Patheon's MOVA Pharmaceutical Corporation, to secure a long-term supply for Keflex products beyond the transitional period.

Keflex is a first-generation cephalosporin approved for treatment of several types of bacterial infections. Keflex is most commonly used in the treatment of uncomplicated skin and skin structure infections and, to a lesser extent, upper respiratory tract infections. Keflex is among the most prescribed antibiotics in the U.S., however, generic competition is intense, and a high percentage of all Keflex prescriptions are substituted by generic versions of cephalexin, the active ingredient in Keflex. We have the exclusive U.S. rights to manufacture, sell and market Keflex pursuant to a purchase agreement with Eli Lilly and Company. We market Keflex in the U.S. to healthcare practitioners, pharmacists, pharmaceutical wholesalers and retail pharmacy chains.

<u>Keflex Products</u>	<u>Key Indication(s)</u>	<u>Status</u>	<u>Marketing Rights</u>
Keflex Capsules — 250 mg and 500 mg	Skin and skin structure infections; upper respiratory tract infections	FDA-approved	U.S. and Puerto Rico rights
Keflex Powder for Oral Suspension — 125 mg and 250 mg	Skin and skin structure infections; upper respiratory tract infections	FDA-approved	U.S. and Puerto Rico rights
Keflex Line Extension products(1)	Skin and skin structure infections; upper respiratory tract infections	Pending FDA approval (1)	U.S. and Puerto Rico rights

(1) On December 20, 2005, we submitted a supplemental NDA (sNDA) to the Food & Drug Administration requesting approval of certain Keflex line extension products.

In addition to assuming sales and marketing responsibilities for Keflex, we have initiated a research program with the goal of developing a once-a-day cephalexin product utilizing our proprietary once-a-day PULSYS dosing technology. In the event we are able to develop and commercialize a PULSYS-based Keflex product, another cephalexin product relying on the acquired NDAs, or other pharmaceutical products using the acquired trademarks, Eli Lilly will be entitled to royalties on these new products. Royalties are payable on a new product by new product basis for five years following the first commercial sale for each new product, up to a maximum aggregate royalty per calendar year. All royalty obligations with respect to any defined new product cease after the fifteenth anniversary of the first commercial sale of the first defined new product.

Our Product Pipeline

The following tables summarize the antibiotic compounds we have in clinical trials and preclinical development. We expect that these compounds will serve as the basis for drug products or, with additional clinical development, drug combination products. Each of our preclinical product candidates is still in the early stage of development. Due to our on-going research and development efforts, additional or alternative compounds may be selected to replace or supplement the compounds described below.

<u>PULSYS Product Candidate / Program</u>	<u>PULSYS Clinical Development Programs</u>			
	<u>Key Indication(s)</u>	<u>Current Therapy</u>	<u>Targeted PULSYS Added Value</u>	<u>Program Status(1)</u>
Amoxicillin — Adult	Pharyngitis/tonsillitis	10-14 days, two or three times daily	10 days, once-daily, lower dose(2)	Phase III
Keflex (cephalexin) — Adult	Skin and skin structure infections	7-14 days, two to four times daily	Once-daily, lower dose,	Phase I
Pediatric Pharyngitis Program	Pharyngitis/tonsillitis	10-14 days, two or three times daily	10 days, once-daily, lower dose, improved convenience	Phase I

(1) For an explanation of the terms Preclinical, Phase I, Phase I/II and Phase III, please refer to the information under the heading "Government Regulation" below. Each of the product candidates above is discussed in more detail in the next section below.

strep throat trial suggest the convenience and transportability of our sprinkle product may be beneficial features of our sprinkle formulation. Regardless of the antibiotic selected for our pediatric pharyngitis program, we expect to utilize our sprinkle presentation as the method of dosing our product. We believe the market opportunity for a pediatric strep throat product is substantial, as more than half of the strep throat market is believed to be represented by pediatric patients.

Other Possible Pulsatile Product Candidates

Our current focus is on the antibiotic product candidates that include amoxicillin and Keflex. We have also identified additional product candidates which we believe could be developed for delivery in a pulsatile manner. The timing of further development work on these candidates depends on our resources as well as our evaluation of the commercial potential of the products.

PULSYS Preclinical Development Programs

Advancis has identified several additional opportunities to apply PULSYS technology to develop individual and combination antibiotic products which we believe could have application against the following indications:

- Sinusitis
- Chronic Bronchitis
- Acute Otitis Media
- Urinary Tract Infections
- Community-acquired Methicillin Resistant *Staphylococcus aureus* (MRSA)

We have conducted preclinical studies evaluating the bacterial killing efficiency of several antibiotics and antibiotic combinations dosed in a pulsatile manner. Based on these studies, along with the consultation of our scientific advisors, we believe we may be able to utilize our PULSYS technology in the creation of antibiotic product candidates that target some of the most common uses of antibiotics. These uses include: sinusitis, chronic bronchitis, acute otitis media, urinary tract infections, and community-acquired methicillin resistant *Staphylococcus aureus* (MRSA).

We may also explore the use of our pulsatile dosing approach beyond antibiotics to other therapeutic categories, such as antivirals and antifungals. Although we have not tested the effectiveness of pulsatile dosing for these applications, we believe that our approach may yield benefits similar to those we have found for the treatment of bacterial infections.

Collaboration Agreements

Termination of Our Collaboration with Par Pharmaceutical for Amoxicillin PULSYS

In May 2004, we entered into an agreement with Par Pharmaceutical to collaborate in the further development and commercialization of a PULSYS-based amoxicillin product. Under the terms of the agreement, we conducted the development program, including the manufacture of clinical supplies and the conduct of clinical trials, and were responsible for obtaining regulatory approval for the product. We were to own the product trademark and to manufacture or arrange for supply of the product for commercial sales. Par was to be the sole distributor of the product. Both parties were to share commercialization expenses, including pre-marketing costs and promotion costs, on an equal basis. Operating profits from sales of the product were also to be shared on an equal basis. Under the agreement, we received an upfront fee of \$5.0 million and a commitment from Par to fund all further development expenses. Development expenses incurred by us were to be partially funded by quarterly payments aggregating \$28 million over the period of July 2004 through October 2005, of which up to \$14 million is contingently refundable.

Revenue related to the receipt of the quarterly payments from Par was recognized based on actual costs incurred as the work was performed, limited to the minimum amounts expected to be received under the agreement and excluding amounts contingent on future events or that were contingently refundable, with the balance of cash received in excess of revenue recognized recorded as deferred revenue. The excess of the development costs incurred by us over the quarterly payments made by Par was to be funded subsequent to commercialization, by the distribution to us of Par's share of operating profits until the excess amount had been reimbursed. We did not record any amounts as revenue on a current basis that were dependent on achievement of future operating profits.

On August 3, 2005, we were notified by Par of its decision to terminate the Amoxicillin PULSYS collaboration agreement. We received from Par the \$4.75 million development funding quarterly payment due in July 2005 and expect no further payments under the collaboration. Under certain circumstances, the termination clauses of the agreement may entitle Par to receive a share of net profits up to one-half of their \$23.25 million funding of the development of certain Amoxicillin PULSYS products, should a product covered by the agreement be successfully commercialized. Accordingly, in the third quarter we retained deferred revenue of \$11.625 million related to the agreement, and accelerated the recognition into current revenue of the remaining balance of \$2.4 million of deferred reimbursement revenue.

Revenue related to the \$5.0 million upfront fee was being amortized into contract revenue on a straight-line basis over the estimated development period. As a result of the termination, we recognized the remaining deferred revenue balance of \$3.2 million related to the upfront fee as revenue in the third quarter of 2005.

Termination of the Collaboration with GlaxoSmithKline

In July 2003, we entered into a license agreement with GlaxoSmithKline (GSK) pursuant to which we licensed patents and PULSYS technology to GSK for use with its Augmentin (amoxicillin/clavulanate combination) products and with limited other amoxicillin products. Under the agreement, GSK was responsible, at its cost and expense, to use commercially reasonable efforts for the clinical development, manufacture and sale of the licensed products. We received an initial non-refundable payment of \$5 million from GSK upon signing of the agreement, a \$3 million payment upon achievement of the first milestone, and would have been entitled to receive additional milestone payments from GSK not to exceed an aggregate of \$49 million if it achieved certain product development goals. In addition, we were eligible to receive royalty payments on the commercial sale of products developed under the agreement. We could have also received sales milestone payments of up to \$50 million if specified annual sales goals were achieved.

The agreement could be terminated at any time by GSK upon relatively short notice. Our receipt of milestone payments, royalty payments and sales milestone payments under the agreement depended on the ability of GSK to develop and commercialize the products covered by the agreement and was subject to certain conditions and limitations. On October 15, 2004, we were notified that GSK would terminate the collaboration, effective December 15, 2004. As a result of the termination, we accelerated the recognition of the remaining deferred revenue of approximately \$3.2 million related to the collaboration during the fourth quarter of 2004. The termination will have no other effects on our financial position.

Collaboration with Par Pharmaceutical for Generic Clarithromycin

In September 2003, we entered into an agreement pursuant to which we licensed to Par Pharmaceutical the distribution and marketing rights to our generic formulation of Abbott's Biaxin XL (extended release clarithromycin). During the third quarter of 2004, we conducted bioequivalence studies on two revised formulations of the generic product, with both formulations failing to achieve bioequivalence. We concluded that due to the non-core nature of the product, the expense involved in the development of additional formulations, the continued redirection of our resources required to pursue the product, and the reduced market potential given the emergence of competing products, we would discontinue further development work on the product.

Sales and Marketing

We currently have a small sales and marketing staff supporting the sale of the Keflex brand of cephalexin to national accounts. Keflex is primarily sold directly to pharmaceutical wholesalers. In the pharmaceutical industry

there are a limited number of major wholesalers responsible for the majority of sales. Product sales of Keflex to Cardinal Health Inc., McKesson Corporation, and AmerisourceBergen Corporation represented approximately 94 percent of our net revenue from Keflex in 2005.

We are currently developing expanded commercialization plans for our Keflex line of products and could leverage that capability should we be successful in gaining marketing approval for Amoxicillin PULSYS. For both Keflex and Amoxicillin PULSYS, we expect to target high-volume prescribers with a community-based sales force. We intend to build our internal sales capability to enable us to sell and market Keflex and our proprietary PULSYS products in concentrated markets. We expect to also use a contract sales organization to supplement our internal capabilities, especially during the early stages of our sales force development.

In February 2006, we entered into marketing agreements with third parties to assist in the sales and marketing of our anticipated new Keflex line extension products. We filed a supplemental New Drug Application (sNDA) with the FDA for the new products in December 2005, and expect to receive action on the application in April 2006. Should we receive approval in April, we believe we would then be in a position to hire internal sales managers, contract with third party contract sales organizations, and then launch our new Keflex products in the second half of 2006.

We expect to hire up to as many as eight internal divisional sales managers and to sign agreements with contract sales organizations whereby we would be directing the selling efforts of approximately 60 to 75 sales representatives who would be dedicated to the promotion of our new Keflex line extension products. Final hiring decisions and contract sales agreements are expected to be completed only upon the approval of the new Keflex products.

We believe that a significant percentage of prescriptions for first-line, broad-spectrum antibiotics is written by high-volume prescribers who can be reached by a community-based sales force. Over time, we intend to expand our sales and marketing capabilities to provide even greater support of our target audience. We may also enter into agreements with other parties to capitalize on their sales and marketing capabilities in order to optimally market our products.

We currently manage the distribution of Keflex, including warehousing and shipping, through Integrated Commercialization Solutions, a division of AmerisourceBergen Corporation. If we successfully develop and receive regulatory approval for additional product candidates, we intend to continue to distribute all approved products through third-party vendors.

If we successfully develop and receive regulatory approval to market additional product candidates, we believe we will have to substantially expand our sales and marketing capabilities and/or enter into partnerships with other pharmaceutical companies to successfully commercialize our product candidates. We will need to successfully recruit sales and marketing personnel and build a sales and marketing infrastructure to successfully commercialize Amoxicillin PULSYS and any additional products or product candidates that we develop, acquire or license. Our future profitability will depend in part on our ability to develop additional sales and marketing capabilities to commercialize our future products to our target audiences.

Competition

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies, as well as smaller emerging companies. Our main competitors are:

- Large pharmaceutical companies, such as Pfizer, GlaxoSmithKline, Wyeth, Bristol-Myers Squibb, Merck, Johnson & Johnson, Roche, Schering-Plough, Novartis, sanofi-aventis, Abbott Laboratories, AstraZeneca, and Bayer, that may develop new drug compounds that render our drugs obsolete or noncompetitive.
- Smaller pharmaceutical and biotechnology companies and specialty pharmaceutical companies engaged in focused research and development of anti-infective drugs, such as Trimeris, Vertex, Gilead Sciences, Cubist, Basilea, InterMune, King, and others.
- Drug delivery companies, such as Johnson & Johnson's Alza division, Biovail and SkyePharma, which may develop a dosing regimen that is more effective than pulsatile dosing.

- Generic drug companies, such as Teva, Ranbaxy, IVAX, Sandoz and Stada, which produce low-cost versions of antibiotics that may contain the same active pharmaceutical ingredients as our PULSYS product candidates.

There are many approved antibiotics available to treat bacterial conditions in the United States. Our product Keflex, and products that are in development, will compete with other available products based primarily on:

- efficacy
- safety
- tolerability
- acceptance by doctors
- patient compliance and acceptance
- patent protection
- convenience
- price
- insurance and other reimbursement coverage
- distribution
- marketing
- adaptability to various modes of dosing

Our Keflex brand of cephalexin faces significant competition from generic distributors of cephalexin capsules and suspension. Currently, a significant portion of the prescriptions written for Keflex are substituted at the pharmacy with generic versions of Keflex, supplied through leading generic drug manufacturers including Teva, Stada, IVAX, Ranbaxy, and others.

In some instances our novel products that utilize our PULSYS technology may compete against non-pulsatile drug products that share the same active ingredient, but are less convenient or require more cumbersome administration schedules. A number of these non-pulsatile drug products are available in generic form, which are usually substantially less expensive than the branded version. Companies such as Teva, Ranbaxy, IVAX, Sandoz and Stada, and others are major manufacturers and distributors of generic versions of antibiotics with whom we may compete in the future.

New developments, including the development of methods of preventing the incidence of disease, such as vaccines, occur rapidly in the pharmaceutical industry. These developments may render our product candidates or technologies obsolete or noncompetitive.

Many of our competitors possess greater financial, managerial and technical resources and have established reputations for successfully developing and marketing drugs, all of which put us at a competitive disadvantage. Our competitors may be able to apply their resources and capabilities to develop and commercialize products that have distinct, enhanced, or perceived advantages versus our products. The competitors may be in a position to devote greater resources in the sales, marketing, and distribution of these products and therefore considerably impact our ability to successfully commercialize our own products.

Manufacturing

We currently rely on third-party contract manufacturers to produce sufficient quantities of our product candidates for use in our preclinical studies and clinical trials. We believe that our initial focus on the production of improved formulations of approved and marketed drugs will reduce the risk and time involved in the development of manufacturing capabilities because production of these drugs involves well-established and well-accepted manufacturing techniques and processes. We intend to continue to rely upon third-party contract manufacturers for production of our clinical and commercial supplies. The use of third-parties for these activities allows us to

minimize our initial capital investment and reduce the risk that would be associated with the establishment of our own commercial manufacturing and distribution operations. With the possible transition to non-beta lactam products, we anticipate that our pilot facility could satisfy our drug production needs for clinical supplies through at least Phase II and, in some cases, through Phase III clinical trials.

In December 2004, we entered into a commercial supply agreement with Ceph International Corporation, a wholly owned subsidiary of Patheon's MOVA Pharmaceutical Corporation, to secure a long-term supply for our Keflex brand of products. This agreement provides for commercial supply of our Keflex product beyond the transitional period agreed to by Eli Lilly as part of our June 2004 acquisition.

In April 2005, we entered into agreements under which Stada Production Ireland Limited ("SPI"), previously known as the manufacturing division of Clonmel Healthcare Limited, a subsidiary of STADA Arzneimittel AG, will provide us with commercial supply of our Amoxicillin PULSYS products currently being evaluated in our Phase III clinical trial. Under the agreements, we secured supply for the commercial phase of our Amoxicillin PULSYS products pending the successful completion of clinical trials and regulatory approval. SPI has capacity in place to cover current projected needs for an initial commercial phase, with additional capacity for growth. In addition to commercial supply, Advancis and SPI have also finalized an agreement for technology transfer, clinical/stability batches and commercial scale-up and validation, as well as an agreement covering Advancis-funded facility build-out and equipment additions to support the commercial manufacturing program.

In connection with our manufacturing activities, we generate hazardous waste. We are subject to federal and state regulation regarding the disposal of hazardous and potentially hazardous waste. We may incur costs to comply with such regulations now or in the future.

Patent and Intellectual Property Protection

Our success depends in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. We seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Further, all of our employees have executed agreements assigning to us all rights to any inventions and processes they develop while they are employed by us.

In addition, we intend to use license agreements to access external products and technologies, as well as to convey our own intellectual property to others. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. Protection of our intellectual property rights is subject to a number of risks.

We currently own 19 issued U.S. patents and 23 U.S. patent applications. Our issued patents cover certain compositions and methods using pulsatile dosing. We also own 56 foreign-filed patent applications, which correspond to our U.S. patents and applications. We also own three International (PCT) patent applications, each of which International (PCT) patent applications we anticipate converting into several individually foreign-filed patent applications to further correspond to our U.S. patents and applications.

Government Regulation

We are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and promotion of drugs under the Federal Food, Drug and Cosmetic Act and the Public Health Services Act, and by comparable agencies in foreign countries. FDA approval is required before any dosage form of any new drug, a generic equivalent of a previously approved drug, or a new combination of previously approved drugs, can be marketed in the United States. All applications for FDA approval must contain information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control.

New Drug Application Process

The process required by the FDA before a new drug may be marketed in the United States generally involves:

- Completion of preclinical laboratory and animal testing.
- Submission of an investigational new drug application (IND) which must become effective before the commencement of clinical trials.
- Performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product's intended use.
- Submission to and approval by the FDA of a New Drug Application (NDA).

PRECLINICAL: Preclinical studies generally include laboratory evaluation of product chemistry, formulation and stability, as well as animal studies, to assess the safety and efficacy of the product. Preclinical trials also provide a basis for design of human clinical studies.

Human clinical trials are typically conducted in three sequential phases which may overlap:

PHASE I: During Phase I studies, the drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

PHASE II: During Phase II studies, the drug is introduced to patients that have the medical condition that the drug is intended to treat. Phase II studies are intended to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Phase II studies may often be combined with Phase I studies (referred to as Phase I/II studies) in certain instances when safety issues and questions of absorption, metabolism, distribution and excretion are well-established.

PHASE III: When Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population, often at geographically dispersed clinical study sites.

The drug sponsor, the FDA or the institutional review board at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a concern that the subjects are being exposed to an unacceptable health risk.

The results of product development, preclinical animal studies and human studies are submitted to the FDA as part of the NDA. The NDA also must contain extensive manufacturing information. The FDA may approve or disapprove the NDA if applicable FDA regulatory criteria are not satisfied or it may require additional clinical data to continue to evaluate the NDA.

In our NDA submissions, we intend to rely, in part, on prior FDA approvals of the antibiotic ingredients used in our products and on data generated by other parties which help to demonstrate the safety and effectiveness of those ingredients. In the case of products that we may develop in conjunction with sponsors of previously approved products, we expect that we will have a specific right of reference to the data contained in the prior applications. In any case in which we do not have a specific right of reference from the sponsor of the previously approved product, we anticipate our NDA submissions would be covered by Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. All data necessary to satisfy the FDA of the safety and effectiveness of our own versions of these products will have to be generated by or for us and submitted to the FDA in support of our applications. These data are expected to include data establishing the safety and efficacy of the pulsatile dosage form and any other differences between the dosage form and the conditions for use of our products and the dosage form and conditions for use of the previously approved products. In the case of antibiotic ingredients not previously approved to be manufactured and sold in the combinations that we propose, it will also be necessary for us to satisfy the FDA's combination drug policy with data establishing that each active component contributes to the effectiveness of the combination and that the dosage of each component is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy. In its review of our NDA submissions, the FDA will have broad discretion to require us to generate data on these matters, and it is impossible to predict the number or nature of the studies that may be

the fiscal year ended December 31, 2003. Our losses to date have resulted principally from research and development costs related to the development of our product candidates, the purchase of equipment and establishment of our facilities and general and administrative costs related to our operations.

We expect to incur substantial losses for the foreseeable future as a result of increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials, and regulatory compliance activities.

Our chances for achieving profitability will depend on numerous factors, including success in:

- developing and testing product candidates;
- achieving milestones under our collaboration agreements;
- receiving regulatory approvals;
- developing proprietary antibiotic products;
- commercializing our products; and
- establishing our competitive position.

Many of these factors will depend on circumstances beyond our control. We cannot assure you that we will ever become profitable.

Substantially all of our product candidates are based on a finding that could ultimately prove to be incorrect, or could have limited applicability.

Substantially all of our product candidates are based on our finding that bacteria exposed to antibiotics in front-loaded, rapid sequential bursts are eliminated more efficiently and effectively than those exposed to presently available treatment regimens. Ultimately, our finding may be incorrect, in which case our pulsatile drugs would not differ substantially from competing drugs and may be inferior to them. If these products are substantially identical or inferior to products already available, the market for our pulsatile drugs will be reduced or eliminated.

Even if pulsatile dosing is more effective than traditional dosing, we may be unable to apply this finding successfully to a substantial number of products in the anti-infective market. Our preliminary studies indicate that pulsatile dosing may not provide superior performance for all types of antibiotics. Additionally, we have not conducted any studies with anti-viral or anti-fungal medications. If we cannot apply our technology to a wide variety of antibiotics or other anti-infectives, our potential market will be substantially reduced.

Our delivery technology may not be effective, which would prevent us from commercializing products that are more effective than those of our competitors.

Even if we are correct that pulsatile dosing is more effective than traditional dosing of antibiotics, our delivery technology must be effective in humans such that the pulsatile administration of drugs are at levels that prove effective in curing infections. If our PULSYS delivery technology is not effective in delivering rapid bursts of antibiotics, or is unable to do so at an appropriate concentration and we are not able to create an alternative delivery method for pulsatile dosing that proves to be effective, we will be unable to capitalize on any advantage of our discovery. Should this occur, our pulsatile product candidates may not be more effective than those of our competitors, which may decrease or eliminate market acceptance of our products.

If a competitor produces and commercializes an antibiotic that is superior to our pulsatile antibiotics, the market for our potential products would be reduced or eliminated.

We have devoted a substantial amount of our research efforts and capital to the development of pulsatile antibiotics. Competitors are developing or have developed new drugs that may compete with our pulsatile antibiotics. For example, sanofi-aventis recently launched Ketek, a drug that belongs to a new class of antibiotics known as ketolides. This antibiotic may compete against our pulsatile antibiotics in the treatment of upper respiratory tract infections. A number of pharmaceutical companies are also developing new classes of compounds,

such as oxazolidinones, that may also compete against our pulsatile antibiotics. In addition, other companies are developing technologies to enhance the efficacy of antibiotics by adding new chemical entities that inhibit bacterial metabolic function. If a competitor produces and commercializes an antibiotic or method of delivery of antibiotics that provides superior safety, effectiveness or other significant advantages over our pulsatile antibiotics, the value of our pulsatile drugs would be substantially reduced. As a result, we would need to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. In the event we are unable to establish new product targets, we will be unable to generate sources of revenue.

We have not commissioned an extensive third party patent infringement, invalidity and enforceability investigation on pulsatile dosing and we are aware of one issued patent covering pulsatile delivery.

Our patents, prior art and infringement investigations were primarily conducted by our senior management and other employees. Although our patent counsel has consulted with management in connection with management's intellectual property investigations, our patent counsel has not undertaken an extensive independent analysis to determine whether our pulsatile technology infringes upon any issued patents or whether our issued patents or patent applications covering pulsatile dosing could be invalidated or rendered unenforceable for any reason. We are aware of one issued patent owned by a third party that covers certain aspects of delivering drugs by use of two delayed release pulses. The patent covers a drug delivery system employing two delayed release pulses using two polymers. The claims made by this patent could be argued to cover certain aspects of our technology. However, we believe that we will be able to manufacture and market formulations of our pulsatile products without infringing any valid claims under this patent. Any reformulation of our products, if required, could be costly and time-consuming and may not be possible. We cannot assure you that a claim will not be asserted by such patent holder or any other holder of an issued patent that any of our products infringe their patent or that our patents are invalid or unenforceable. We may be exposed to future litigation by third parties based on claims that our products or activities infringe the intellectual property rights of others. We cannot assure you that, in the event of litigation, any claims would be resolved in our favor. Any litigation or claims against us, whether or not valid, may result in substantial costs, could place a significant strain on our financial resources, divert the attention of management and harm our reputation. In addition, intellectual property litigation or claims could result in substantial damages and force us to do one or more of the following:

- cease selling, incorporating or using any of our products that incorporate the challenged intellectual property;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our products, which would be costly and time-consuming and may not be possible.

We have not sought patent protection for certain aspects of our technology.

We have not filed for patent protection with respect to specific formulations, materials (including inactive ingredients) or manufacturing process approaches that are incorporated in our individual pulsatile antibiotic products, and we may not seek such patent coverage in the future. In producing our pulsatile antibiotics, we expect to use general formulation techniques used in the industry that would be modified by us and which would, therefore, include know-how and trade secrets that we have developed. We cannot be certain that a patent would issue to cover such intellectual property and currently, we would prefer to keep such techniques and know-how as our trade secrets. In the event a competitor is able to develop technology substantially similar to ours and patent that approach, we may be blocked from using certain of our formulations or manufacturing process approaches, which could limit our ability to develop and commercialize products.

If we are unable to develop and successfully commercialize our product candidates, we may never achieve profitability.

We have not commercialized any pulsatile products or recognized any revenue from PULSYS product sales. With the exception of our Amoxicillin PULSYS product, all of our pulsatile drugs are in early stages of development with a total of only four pulsatile product candidates having been tested in Phase I/II clinical trials

to date. Our Amoxicillin PULSYS product is currently in a Phase III clinical trial, however, we must successfully complete this Phase III clinical trial and obtain regulatory approval for our pulsatile products before we are able to commercialize pulsatile products and generate revenue from their sales. We expect that we must conduct significant additional research and development activities on our other pulsatile products successfully completing preclinical, Phase I, Phase I/II or Phase II, and Phase III clinical trials before we will be able to receive final regulatory approval to commercialize these pulsatile products. Even if we succeed in developing and commercializing one or more of our pulsatile drugs, we may never generate sufficient or sustainable revenue to enable us to be profitable.

If we do not successfully attract and retain collaborative partners, or our partners do not satisfy their obligations, we will be unable to develop our partnered product candidates.

For certain product candidates, we intend to enter into collaborative arrangements with third parties. These collaborations may be necessary in order for us to:

- fund our research and development activities;
- fund manufacturing by third parties;
- seek and obtain regulatory approvals; and
- successfully commercialize our product candidates.

We cannot assure you that we will be able to enter into collaborative agreements with partners on terms favorable to us, or at all, and any future agreement may expose us to risks that our partner might fail to fulfill its obligations and delay commercialization of our products. We also could become involved in disputes with partners, which could lead to delays in or terminations of our development and commercialization programs and time consuming and expensive litigation or arbitration. Our inability to enter into additional collaborative arrangements with other partners, or our failure to maintain such arrangements, would limit the number of product candidates which we could develop and ultimately, decrease our sources of any future revenues.

If we cannot enter into new licensing arrangements or otherwise gain access to products, our ability to develop a diverse product portfolio could be limited.

A component of our business strategy is in-licensing or acquiring drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories that may be marketed and developed or improved upon using our novel technologies. Competition for promising compounds can be intense and currently we have not entered into any arrangement to license or acquire any drugs from other companies. If we are not able to identify licensing or acquisition opportunities or enter into arrangements on acceptable terms, we will be unable to develop a diverse portfolio of products. Any product candidate that we acquire will require additional research and development efforts prior to commercial sale, including extensive preclinical and/or clinical testing and approval by the FDA and corresponding foreign regulatory authorities. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe, non-toxic and effective or approved by regulatory authorities. In addition, we cannot assure you that any approved products that we develop or acquire will be: manufactured or produced economically; successfully commercialized; widely accepted in the marketplace or that we will be able to recover our significant expenditures in connection with the development or acquisition of such products. In addition, proposing, negotiating and implementing an economically viable acquisition is a lengthy and complex process. Other companies, including those with substantially greater financial, sales and marketing resources, may compete with us for the acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all. In addition, if we acquire product candidates from third parties, we will be dependent on third parties to supply such products to us for sale. We could be materially adversely affected by the failure or inability of such suppliers to meet performance, reliability and quality standards.

Our executive officers and other key personnel are critical to our business and our future success depends on our ability to retain them.

We are highly dependent on the principal members of our scientific and management teams, especially Edward M. Rudnic, our president and chief executive officer. In order to pursue our product development, marketing and commercialization plans, we may need to hire additional personnel with experience in clinical testing, government regulation, manufacturing, marketing and business development. We may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. We are not aware of any present intention of any of our key personnel to leave our company or to retire. However, although we have employment agreements with our executive officers, these employees may terminate their services upon 90 days' advance notice. The loss of any of our key personnel, or the inability to attract and retain qualified personnel, may significantly delay or prevent the achievement of our research, development or business objectives and could materially adversely affect our business, financial condition and results of operations. Although we maintain key man life insurance on Dr. Rudnic, such insurance may not be sufficient to cover the costs of the loss of his services and the expense of recruiting and hiring a new president and chief executive officer.

Our ability to complete clinical trials and ultimately commercialize products will be delayed if we are unable to obtain sufficient APIs or finished products from certain suppliers.

We obtain active pharmaceutical ingredients (APIs) and finished products from certain specialized manufacturers for use in clinical studies that we intend to conduct without assistance from collaborative partners. Although the antibiotics and finished products we use in our clinical studies may be obtained from several suppliers, our applications for regulatory approval may authorize only one supplier as our source. In the event an authorized supplier in an application for regulatory approval loses its regulatory status as an acceptable source or otherwise becomes unable or unwilling to supply the API or finished products to us at a commercially reasonable price, we would need to locate another source. A change to a supplier not previously approved in our application for regulatory approval or an alteration in the procedures or product provided to us by an approved supplier may require formal approval by the U.S. Food and Drug Administration (FDA) before we could use the API in the production of commercial supplies for our products or use the finished product for commercialization. These factors could result in delays in conducting or completing our clinical trials and delay our ability to commercialize products.

Clinical trials for our product candidates may be delayed due to our dependence on third parties for the conduct of such trials.

We have limited experience in conducting and managing clinical trials. We rely, and will continue to rely, on third parties, including clinical research organizations and outside consultants, to assist us in managing and monitoring clinical trials. Our reliance on these third parties may result in delays in completion of, or the failure to complete, these trials if they fail to perform their obligations under our agreements.

If clinical trials for our products are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines.

We must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans before we can obtain regulatory approvals for their commercial sale. In addition, we will also need to demonstrate through clinical trials any claims we may wish to make that our product candidates are comparable or superior to existing products. For drug products which are expected to contain active ingredients in fixed combinations that have not been previously approved by the FDA, clinical studies may also need to be conducted in order to establish the contribution of each active component to the effectiveness of the combination in an appropriately identified patient population.

Conducting clinical trials is a lengthy, time-consuming and expensive process. Currently, we have one Amoxicillin PULSYS product in a Phase III clinical trial for adults and adolescents. We expect to have results from the adults and adolescents trial in the third quarter of 2006. For our other products we have not completed preclinical studies and initial clinical trials (Phase I, Phase I/II or Phase II) to extrapolate proper dosage for Phase III clinical

efficacy trials in humans. In the event we incorrectly identify a dosage as appropriate for human clinical trials, any results we receive from such trials may not properly reflect the optimal efficacy or safety of our products and may not support approval in the absence of additional clinical trials using a different dosage.

The commencement and rate of completion of clinical trials for our products may be delayed by many factors, including:

- lack of efficacy during the clinical trials;
- unforeseen safety issues;
- slower than expected rate of patient recruitment; or
- government or regulatory delays.

The results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. Although a new product may show promising results in preclinical and initial clinical trials, it may subsequently prove unfeasible or impossible to generate sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical studies are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may encounter regulatory delays or rejections as a result of many factors, including results that do not support our claims, perceived defects in the design of clinical trials and changes in regulatory policy during the period of product development. Our business, financial condition and results of operations may be materially adversely affected by any delays in, or termination of, our clinical trials or a determination by the FDA that the results of our trials are inadequate to justify regulatory approval.

We will need additional capital in the future. If additional capital is not available, we may be forced to delay or curtail the development of our product candidates.

We anticipate that our existing capital resources and expected product sales will enable us to maintain our current operations for at least the next 12 months. We may need additional capital to fund our operations beyond 2006. Our requirements for additional capital could be substantial and will depend on many other factors, including:

- payments received under future collaborative partner agreements;
- continued progress of research and development of our pulsatile drugs;
- our ability to acquire or license drugs from others for use with PULSYS;
- costs associated with protecting our intellectual property rights;
- development of sales and marketing capabilities; and
- market acceptance of our products.

We have no significant committed sources of additional capital. To the extent our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds to continue the development of our product candidates. We cannot assure you that funds will be available on favorable terms, if at all. To the extent we raise additional capital through the sale of securities, the issuance of those securities could result in dilution to our stockholders. In addition, if we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities. If adequate funds are not available, we may be required to curtail significantly our development and commercialization activities.

We could be forced to pay substantial damage awards if product liability claims that may be brought against us are successful.

The use of any of our product candidates in clinical trials, and the sale of any approved products, may expose us to liability claims and financial losses resulting from the use or sale of our products. We have obtained limited product liability insurance coverage for our clinical trials, which we believe is adequate to cover our present

activities. However, such insurance may not be adequate to cover any claims made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses.

If our PULSYS products are not accepted by the market, our revenues and profitability will suffer.

Even if we obtain regulatory approval to market our PULSYS products, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any pharmaceutical product that we develop will depend on a number of factors, including:

- demonstration of clinical efficacy and safety;
- cost-effectiveness;
- potential advantages over alternative therapies;
- reimbursement policies of government and third-party payors; and
- effectiveness of our marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners.

Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by major pharmaceutical companies, biotechnology companies and manufacturers of generic drugs. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept and use any product candidates that we or our collaborative partners develop. To the extent current antibiotics already successfully treat certain infections, physicians may not be inclined to prescribe our pulsatile drugs for the same indications. If our products do not achieve significant market acceptance, we will not be able to generate significant revenues or become profitable.

Because we depend on a single manufacturer for Keflex, we may be unable to obtain sufficient quantities of these products at commercially acceptable rates.

We obtained our Keflex products from Eli Lilly under a manufacturing agreement that expired in December 2005. We have transitioned the manufacturing of our Keflex products to Ceph International Corporation, a wholly-owned subsidiary of Patheon's MOVA Pharmaceutical Corporation. Although we believe that the API and finished products for Keflex could be obtained from several suppliers, our applications for regulatory approval currently authorize only Ceph as our source. In the event that Ceph is unable to supply the products to us at a commercially reasonable price or breaches its agreement with us, or if Ceph loses its regulatory status as an acceptable source, we would need to locate another source. A change to a supplier not previously approved or an alteration in the procedures or product provided to us by an approved supplier may require formal approval by the FDA before the product could be sold. These factors could limit our ability to sell Keflex and would materially adversely affect our revenues.

We rely upon a limited number of pharmaceutical wholesalers and distributors, which could impact our ability to sell our Keflex product.

We rely largely upon specialty pharmaceutical distributors and wholesalers to deliver Keflex to end users, including physicians, hospitals, and pharmacies. There can be no assurance that these distributors and wholesalers will adequately fulfill the market demand for Keflex, nor can there be any guarantee that these service providers will remain solvent. Given the high concentration of sales to certain pharmaceutical distributors and wholesalers, we could experience a significant loss if one of our top customers were to declare bankruptcy or otherwise become unable to pay its obligations to us.

We are subject to therapeutic equivalent substitution, Medicaid reimbursement and price reporting.

The cost of pharmaceutical products continues to be a subject of investigation and action by governmental agencies, legislative bodies and private organizations in the U.S. and other countries. In the U.S., most states have enacted legislation requiring or permitting a dispensing pharmacist to substitute a generic equivalent to the

prescribed drug. Federal legislation requires pharmaceutical manufacturers to pay to state Medicaid agencies prescribed rebates on drugs to enable them to be eligible for reimbursement under Medicaid programs. Federal and state governments continue to pursue efforts to reduce spending in Medicaid programs, including restrictions on amounts agencies will reimburse for certain products. In addition, some states are seeking rebates in excess of the amounts required by federal law, and there are federal legislative proposals to expand current Medicaid rebates. We also must give discounts or rebates on purchases or reimbursements of Keflex by certain other federal and state agencies and programs. Our ability to earn sufficient returns on Keflex depends, in part, on the availability of reimbursements from third party payers, such as health insurers, governmental health administration authorities and other organizations and the amount of rebates payable under Medicaid programs.

Our ability to conduct clinical trials will be impaired if we fail to qualify our clinical supply manufacturing facility and we are unable to maintain relationships with current clinical supply manufacturers or enter into relationships with new manufacturers.

We currently rely on several contractors to manufacture product samples for our clinical studies. In the fourth quarter of 2003, we completed construction of a manufacturing facility for production of clinical supplies sufficient for use through our Phase II and, in some cases, Phase III clinical trials. We expect this facility to be qualified and operational in the future. We have no experience qualifying manufacturing facilities and we may not be able to qualify the facility. If we are unsuccessful in qualifying our own manufacturing facility and fail to maintain our relationships with our current clinical supply manufacturers or enter into relationships with new manufacturers, we will be unable to conduct our clinical trials effectively.

We intend to rely on third parties to manufacture products that we intend to sell through our own commercialization and sales efforts. We believe that there are a variety of manufacturers that we may retain to produce these products. However, once we retain a manufacturing source, if we are unable to maintain our relationship with such manufacturer, qualifying a new manufacturing source will be time consuming and expensive, and may cause delays in the development of our products.

If we fail to establish sales, marketing, and distribution capabilities, or fail to enter into arrangements with third parties, we will not be able to commercialize our products.

We have limited sales, marketing, and distribution capabilities. In order to commercialize any product candidates that receive final regulatory approval, we must considerably expand our commercial capabilities or make arrangements with third parties to perform these services for us. In order to market any of our product candidates directly, we must considerably expand our commercial infrastructure, including distribution, marketing, and sales personnel. The expansion or contracting of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts. To the extent that we enter into sales and marketing arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to expand sales, marketing and distribution capabilities, or fail to enter into arrangements with third parties, we will experience delays in product sales and incur increased costs.

Risks Related to our Industry

Any inability to protect our intellectual property could harm our competitive position.

Our success will depend in part on our ability to obtain patents and maintain adequate protection of other intellectual property for our technologies and products in the U.S. and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate our competitive advantage. Further, the laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the U.S., and we may encounter significant problems in protecting our proprietary rights in these foreign countries.

The patent positions of pharmaceutical and biotechnology companies, including our patent positions, involve complex legal and factual questions and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our

proprietary rights from unauthorized use by third parties only to the extent that we cover our proprietary technologies with valid and enforceable patents or we effectively maintain such proprietary technologies as trade secrets. We will apply for patents covering both our technologies and product candidates as we deem appropriate. We may fail to apply for patents on important technologies or products in a timely fashion, or at all, and in any event, the applications we do file may be challenged and may not result in issued patents. Any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. In addition, if challenged, our patents may be declared invalid. Even if valid, our patents may fail to provide us with any competitive advantages.

We rely upon trade secrets protection for our confidential and proprietary information. We have taken measures to protect our proprietary information; however, these measures may not provide adequate protection. We seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose our proprietary information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

If we do not compete successfully in the development and commercialization of products and keep pace with rapid technological change, we will be unable to capture and sustain a meaningful market position.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. While we are not aware of any company using rapid bursts of antibiotics as a treatment method, there are numerous companies actively engaged in the research and development of anti-infectives.

Our main competitors are:

- Large pharmaceutical companies, such as Pfizer, GlaxoSmithKline, Wyeth, Bristol-Myers Squibb, Merck, Johnson & Johnson, Roche, Schering-Plough, Novartis, sanofi-aventis, Abbott Laboratories, AstraZeneca, and Bayer, that may develop new drug compounds that render our drugs obsolete or noncompetitive.
- Smaller pharmaceutical and biotechnology companies and specialty pharmaceutical companies engaged in focused research and development of anti-infective drugs, such as Trimeris, Vertex, Gilead Sciences, Cubist, Basilea, Intermune, King, and others.
- Drug delivery companies, such as Johnson & Johnson's Alza division, Biovail and SkyePharma, which may develop a dosing regimen that is more effective than pulsatile dosing.
- Generic drug companies, such as Teva, Ranbaxy, IVAX, Sandoz and Stada, which produce low-cost versions of antibiotics that may contain the same active pharmaceutical ingredients as our PULSYS product candidates.

Many of these competitors, either alone or together with their collaborative partners, have substantially greater financial resources and larger research and development staffs than we do. In addition, many of these competitors, either alone or together with their collaborative partners, have significantly greater experience than we do in:

- developing products;
- undertaking preclinical testing and human clinical trials;
- obtaining approvals of products from the FDA and other regulatory agencies; and
- manufacturing and marketing products.

Developments by others may render our product candidates or technologies obsolete or noncompetitive. We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions, and for licenses of products or technology. These competitors, either alone or with their collaborative partners, may succeed in developing technologies or products that are more effective than ours.

If we experience delays in obtaining regulatory approvals, or are unable to obtain or maintain regulatory approvals, we may be unable to commercialize any products.

Our product candidates are subject to extensive and rigorous domestic government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our products are marketed abroad, they will also be subject to extensive regulation by foreign governments. None of our PULSYS product candidates has been approved for sale in the U.S. or any foreign market. The regulatory review and approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. The actual time required for satisfaction of FDA pre-market approval requirements may vary substantially based upon the type, complexity and novelty of the product or the medical condition it is intended to treat. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon a manufacturer's activities. Delays in obtaining regulatory approvals may:

- adversely affect the commercialization of any drugs that we or our collaborative partners develop;
- impose costly procedures on us or our collaborative partners;
- diminish any competitive advantages that we or our collaborative partners may attain; and
- adversely affect our receipt of revenues or royalties.

Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval.

Any required approvals, once obtained, may be withdrawn. Further, if we fail to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process, we may encounter difficulties including:

- delays in clinical trials or commercialization;
- product recalls or seizures;
- suspension of production and/or distribution;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties and criminal prosecutions.

We may rely on future collaborative partners to file investigational new drug applications and generally direct the regulatory approval process for many of our products. These collaborative partners may not be able to conduct clinical testing or obtain necessary approvals from the FDA or other regulatory authorities for any product candidates. If we fail to obtain required governmental approvals, we or our collaborative partners will experience delays in, or be precluded from, marketing products developed through our research.

We and our contract manufacturers also are required to comply with applicable FDA good manufacturing practice regulations. Good manufacturing practice regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our products. We or our contract manufacturers may not be able to comply with the applicable good manufacturing practice requirements and other FDA regulatory requirements. If we or our contract manufacturers fail to comply, we could be subject to fines or other sanctions, or be precluded from marketing our products.

The manufacture and storage of pharmaceutical and chemical products is subject to environmental regulation and risk.

Because of the chemical ingredients of pharmaceutical products and the nature of their manufacturing process, the pharmaceutical industry is subject to extensive environmental regulation and the risk of incurring liability for damages or the costs of remedying environmental problems. We use a number of chemicals and drug substances that can be toxic to humans. These chemicals include acids, solvents and other reagents used in the normal course of our chemical and pharmaceutical analysis, and other materials, such as polymers, inactive ingredients and drug substances, used in the research, development and manufacture of drug products. If we fail to comply with environmental regulations to use, discharge or dispose of hazardous materials appropriately or otherwise to comply with the conditions attached to our operating licenses, the licenses could be revoked and we could be subject to criminal sanctions and/or substantial liability or could be required to suspend or modify our operations.

Environmental laws and regulations can require us to undertake or pay for investigation, clean-up and monitoring of environmental contamination identified at properties that we currently own or operate or that we formerly owned or operated. Further, they can require us to undertake or pay for such actions at offsite locations where we may have sent hazardous substances for disposal. These obligations are often imposed without regard to fault. In the event we are found to have violated environmental laws or regulations, our reputation will be harmed and we may incur substantial monetary liabilities. We currently have insurance coverage that we believe is adequate to cover our present activities. However, this insurance may not be available or adequate to cover any losses arising from contamination or injury resulting from our use of hazardous substances.

Market acceptance of our products will be limited if users of our products are unable to obtain adequate reimbursement from third-party payors.

The commercial success of our product candidates will depend in part on the availability of reimbursement from third-party payors, including government health administrators, managed care providers and private health insurers. Even if we succeed in bringing any of our proposed products to market, we cannot assure you that third-party payors will consider our products cost-effective or provide reimbursement in whole or in part for their use.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors may conclude that our products are less safe, effective or cost-effective than existing products. Therefore, third-party payors may not approve our products for reimbursement.

If third-party payors do not approve our products for reimbursement or fail to reimburse them adequately, sales will suffer as some physicians or their patients will opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payors make reimbursement available, reimbursement levels may not be sufficient for us to realize an appropriate return on our investment in product development.

Moreover, the trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our products. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agencies adopt these proposals, they could materially adversely affect our business, financial condition and results of operations.

Other Risks

HealthCare Ventures V, L.P., HealthCare Ventures VI, L.P. and HealthCare Ventures VII, L.P. have substantial control over our business and the interests of the HealthCare Ventures partnerships may not be consistent with the interests of our other stockholders.

HealthCare Ventures V, L.P. and HealthCare Ventures VI, L.P. currently beneficially own an aggregate of 36.1% of our outstanding common stock. James H. Cavanaugh and Harold R. Werner, members of our board of directors, are general partners of HealthCare Partners V, L.P. and HealthCare Partners VI, L.P., which are the general partners of HealthCare Ventures V, L.P. and HealthCare Ventures VI, L.P., respectively. Accordingly, the

HealthCare Ventures partnerships are able to exert significant influence over all matters requiring stockholder approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, as well as over the day-to-day management of our business. The HealthCare Ventures partnerships may direct our affairs in a manner that is not consistent with the interests of our other stockholders. In addition, this concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination or a sale of all or substantially all of our assets.

Future sales of our common stock, or the perception that these sales may occur, could depress our stock price.

Sales of substantial amounts of our common stock in the public market, or the perception in the public markets that these sales may occur, could cause the market price of our common stock to decline.

This could also impair our ability to raise additional capital through the sale of our equity securities. Selling of a large number of shares by any of our existing shareholders or management shareholders could cause the price of our common stock to decline. Furthermore, if we file a registration statement to offer additional shares of our common stock and have to include shares held by those holders, it could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

Our certificate of incorporation and provisions of Delaware law could discourage a takeover you may consider favorable or could cause current management to become entrenched and difficult to replace.

Provisions in our certificate of incorporation and Delaware law may have the effect of delaying or preventing a merger or acquisition of us, or making a merger or acquisition less desirable to a potential acquirer, even when the stockholders may consider the acquisition or merger favorable. Under the terms of our certificate of incorporation, we are authorized to issue 25 million shares of "blank check" preferred stock, and to determine the price, privileges, and other terms of these shares. The issuance of any preferred stock with superior rights to our common stock could reduce the value of our common stock. In particular, specific rights we may grant to future holders of preferred stock could be used to restrict an ability to merge with or sell our assets to a third party, preserving control by present owners and management and preventing you from realizing a premium on your shares.

In addition, we are subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder's acquisition of our stock was approved in advance by our board of directors. These provisions could affect our stock price adversely.

The price of our common stock has been and will likely continue to be volatile.

Prior to October 2003, there was no public market for our common stock. We cannot predict the extent to which investor interest will lead to the development of an active and liquid trading market in our common stock. The initial public offering price of our common stock was \$10.00 per share. Since our initial public offering, the price of our common stock has been as high as \$10.30 and as low as \$0.86 per share. Some companies that have had volatile market prices for their securities have been subject to securities class action suits filed against them. If a suit were to be filed against us, regardless of the outcome, it could result in substantial costs and a diversion of our management's attention and resources. This could have a material adverse effect on our business, results of operations and financial condition.

We could be forced to pay liquidated damages if we do not maintain the effectiveness of our S-3 registration statement.

In April 2005, we completed a private placement of 6,846,735 shares of our common stock at a price of \$3.98 per share and warrants to purchase a total of 2,396,357 shares of common stock at an exercise price of \$4.78 per share, resulting in gross proceeds of \$27.25 million. Pursuant to the terms of the registration rights agreement, we filed with the SEC a registration statement on Form S-3 covering the resale of common stock. The registration rights agreement provides that if a registration statement is not effective within 60 days of closing, or if we do not

subsequently maintain the effectiveness of the registration statement, then in addition to any other rights the investor may have, we will be required to pay the investor liquidated damages, in cash, equal to one percent per month of the aggregate purchase price paid by such investor.

The SEC declared our Form S-3 effective on June 1, 2005, which was within 60 days of closing. We believe that the events that would lead to a suspension of effectiveness are unlikely to occur. However, if we fail to maintain the effectiveness of the registration statement in the future, liquidated damages could be substantial.

Item 1B. *Unresolved Staff Comments*

None

Item 2. *Properties*

Our principal executive offices are located in an approximately 62,000 square foot facility in Germantown, Maryland. We moved into this facility in May 2003 and completed the transfer of our laboratory function to this facility in December 2003. The lease for this facility expires in June 2013.

In August 2004, we entered into a lease for approximately 53,000 square feet of additional research and development space, in a building adjacent to the Company's existing headquarters in Germantown, Maryland. The lease for this facility expires in May 2013.

We previously had an approximately 8,432 square foot lab and office facility in Gaithersburg, Maryland, the lease for which expired in November 2005. Also, in September 2004 we rented an office of approximately 6,681 square feet for engineering space in Bridgewater, New Jersey under a short-term lease that expires in September 2006.

We believe that our facilities are suitable and adequate to meet our current needs.

Item 3. *Legal Proceedings*

We are not a party to any material pending legal proceedings, other than ordinary routine litigation incidental to our business, except as discussed below.

In December 2003, Aventis and Aventis Pharmaceuticals Inc., now part of sanofi-aventis, brought an action against Advancis in the U.S. District Court for the District of Delaware. The Complaint contains six counts, based upon both federal and state law, alleging, in essence, that we infringed on the plaintiffs' trademark. The plaintiffs seek injunctive relief, as well as unspecified monetary damages. Discovery has been completed, the trial was held in May 2005, and we are currently waiting for the judgment of the court. We believe that the ultimate outcome of this matter will not have a material adverse effect upon our financial position but could possibly have a material adverse effect on our results of operations for a particular period.

Item 4. *Submission of Matters to a Vote of Security Holders*

No matters were submitted to a vote of our security holders during the fourth quarter of the fiscal year ended December 31, 2005.

PART II

Item 5. *Market for Registrant's Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities*

Our common stock has been traded on The Nasdaq National Market under the symbol AVNC since October 17, 2003. The following table sets forth the quarterly high and low sales prices per share of our common stock as reported by Nasdaq for each quarter during the last two fiscal years, commencing on January 1, 2004:

	<u>HIGH</u>	<u>LOW</u>
December 31, 2005:		
Fourth quarter	\$ 1.69	\$1.20
Third quarter	2.75	0.86
Second quarter	5.40	1.70
First quarter	5.42	3.03
December 31, 2004:		
Fourth quarter	\$ 8.60	\$2.50
Third quarter	9.05	6.73
Second quarter	9.74	6.58
First quarter	10.15	7.34

As of February 28, 2006, there were 132 holders of record of our common stock. This figure does not represent the actual number of beneficial owners of our common stock because shares are generally held in "street name" by securities dealers and others for the benefit of individual owners who may vote the shares.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends for the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in current or future financing instruments and such other factors as our board of directors deems relevant.

From October 15, 2003, the effective date of our Registration Statement on Form S-1 (File No. 333-107599), to December 31, 2005, we have used the entire \$54.3 million of the net offering proceeds from our initial public offering, as follows:

Purchase of Keflex intangible assets	\$11,206,000
Purchases of property and equipment	4,768,000
Cash used for debt payments	1,513,000
Cash used in operating activities	<u>36,825,000</u>
Total	<u>\$54,312,000</u>

Item 6. Selected Financial Data

The following selected financial information has been derived from the audited financial statements. The information below is not necessarily indicative of results of future operations and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-K and the financial statements and related notes thereto included in Item 8 of this Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

	For the Years Ended December 31,				
	2005	2004	2003	2002	2001
Statements of Operations Data					
Total revenue	\$ 16,847,690	\$ 11,358,032	\$ 3,625,000	\$ —	\$ —
Cost and expenses:					
Cost of product sales	562,009	169,854	—	—	—
Research and development	39,729,441	33,642,930	16,594,629	10,855,130	5,295,308
Selling, general and administrative	10,515,302	12,219,409	6,427,453	3,323,879	1,958,602
Total expenses	50,806,752	46,032,193	23,022,082	14,179,009	7,253,910
Loss from operations	(33,959,062)	(34,674,161)	(19,397,082)	(14,179,009)	(7,253,910)
Interest income (expense), net	954,193	669,448	88,565	102,629	69,334
Beneficial conversion feature — deemed interest	—	—	(1,666,667)	—	—
Other income or (expense)	16,292	—	—	(47,615)	—
Net loss	(32,988,577)	(34,004,713)	(20,975,184)	(14,123,995)	(7,184,576)
Accretion of issuance costs of mandatorily redeemable convertible preferred stock	—	—	(209,173)	(73,925)	(37,594)
Beneficial conversion feature — deemed dividend to preferred shareholders	—	—	(20,907,620)	—	—
Net loss applicable to common stockholders	\$ (32,988,577)	\$ (34,004,713)	\$ (42,091,977)	\$ (14,197,920)	\$ (7,222,170)
Basic and diluted net loss per share	\$ (1.20)	\$ (1.50)	\$ (7.58)	\$ (16.37)	\$ (12.59)
Shares used in computing net loss per share, basic and diluted	27,421,516	22,684,410	5,554,773	867,239	573,699
Balance Sheet Data at Year-End:					
Unrestricted cash, cash equivalents and marketable securities	\$ 29,431,058	\$ 30,051,937	\$ 65,087,122	\$ 4,059,911	\$16,472,049
Total assets	57,796,892	61,142,140	84,174,843	9,058,523	18,575,075
Long-term debt, including current portion	1,567,412	2,577,387	2,440,588	1,730,934	1,089,882
Mandatorily redeemable convertible preferred stock	—	—	—	28,439,295	25,391,170
Accumulated deficit	(111,095,308)	(78,106,731)	(44,102,018)	(23,126,834)	(9,002,839)
Total stockholders' equity (deficit)	33,342,011	39,738,379	70,149,920	(22,701,459)	(8,701,660)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this annual report on Form 10-K. This discussion may contain forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the "Forward-Looking Statements" and "Factors that May Affect our Business" sections in Part 1, Item 1 and elsewhere in this annual report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

Our Business

Advancis Pharmaceutical Corporation was incorporated in Delaware in December 1999 and commenced operations on January 1, 2000. We are a pharmaceutical company focused on developing and commercializing anti-infective drug products that fulfill unmet medical needs in the treatment of infectious disease. We are developing a portfolio of drugs based on the novel biological finding that bacteria exposed to antibiotics in front-loaded, sequential bursts, or pulses, are killed more efficiently than those exposed to standard antibiotic treatment regimens. We currently have 19 issued U.S. patents covering our proprietary once-a-day pulsatile delivery technology called PULSYS. We have initially focused on developing PULSYS product candidates utilizing approved and marketed drugs that no longer have patent protection or that have patents expiring in the next several years. Our lead pulsatile product candidate, based on the antibiotic amoxicillin, is currently under evaluation in a Phase III clinical trial and our Keflex PULSYS product candidate, based on the antibiotic cephalexin, is currently under evaluation in a Phase I clinical trial. We also have a number of additional PULSYS product candidates in preclinical development. We acquired the U.S. rights to Keflex (cephalexin) from Eli Lilly in 2004. We currently employ a small sales and marketing staff that is supporting the sale of Keflex products to national accounts. In anticipation of the possible introduction of our first pulsatile product, Amoxicillin PULSYS, as well as the possible introduction of Keflex line extension products, we plan to expand our sales and marketing capabilities by working with contract sales organizations or collaborative marketing partners. We have entered into agreements with third-party contract manufacturers for the commercial supply of our products.

Management Overview of Key Developments in 2005

The following is a summary of key events that occurred in 2005.

PULSYS product development and collaborations

- On July 21, 2005, we announced that our pediatric Amoxicillin PULSYS Phase III clinical trial failed to achieve its desired microbiological and clinical endpoints. This pivotal program was designed as a 500-patient, investigator-blind, non-inferiority Phase III trial for a "sprinkle" formulation of Amoxicillin PULSYS for the treatment of pharyngitis/tonsillitis due to Group A streptococcal infections. We had previously announced on June 15, 2005 that our Amoxicillin PULSYS Phase III clinical trial for the treatment of pharyngitis/tonsillitis in adults and adolescents failed to achieve its desired microbiological and clinical endpoints. This pivotal program was designed as a 500 patient, double-blind, double-dummy, non-inferiority Phase III trial for a tablet formulation of Amoxicillin PULSYS for the treatment of pharyngitis/tonsillitis due to Group A streptococcal infections.
- Subsequent to the announcement of our unsuccessful Phase III trial results, we reduced our workforce by approximately 38% in order to reduce operating expenses. We recorded a charge of approximately \$4.0 million in the third quarter for severance costs related to salaries and benefits.
- In each of January, April and August 2005, we received payments of \$4.75 million from Par Pharmaceutical for its quarterly funding due under our Amoxicillin PULSYS collaboration. In August 2005, Par decided to terminate the collaboration. As a result of the termination, we recognized revenue in the third quarter of \$5.6 million that had previously been deferred.
- In September 2005, after extensive study of the data from our recently-concluded unsuccessful Amoxicillin PULSYS Phase III clinical trials, we decided to conduct a new Phase III trial for adults and adolescents,

extending the length of treatment from seven days to 10 days, using the current formulation of Amoxicillin PULSYS.

- In November 2005, we held a pre-Phase III meeting with the FDA to discuss our Phase III trial and regulatory strategy to support product approval for Amoxicillin PULSYS. Based on the outcome of the meeting, we believe that our Phase III trial design and regulatory strategy for approval of Amoxicillin PULSYS for adults and adolescents with pharyngitis/tonsillitis were acceptable to the FDA.
- In November 2005, we began enrolling patients into our new Phase III trial for Amoxicillin PULSYS for adults and adolescents with strep throat. We expect to enroll at least 600 patients into the trial and announce top-line results during the third quarter of 2006.
- In December 2005, we commenced a Phase I clinical trial for development of a once-daily PULSYS version of Keflex.

Marketed Products — Keflex

- In 2005, the first full year of our ownership of the Keflex brand, net sales of our branded capsule and powder for oral suspension Keflex products were approximately \$4.8 million.
- An agreement in principle was reached in August 2005 to sell the U.S. rights to the Keflex brand of cephalexin to a private company. We received a \$1.0 million advance payment from the potential buyer which ensured its exclusive negotiating rights to the product through December 31, 2005. A definitive agreement was never entered into between the parties, and in January 2006, we decided to retain the brand. The agreement in principle expired February 28, 2006.
- We continued development of additional non-PULSYS Keflex line extension products. In December 2005, we filed a supplemental NDA for line extension products. The application was accepted by the FDA in February 2006.

Other Events

- In April 2005, we completed a private placement of 6,846,735 shares of our common stock at a price of \$3.98 per share, and warrants to purchase a total of 2,396,357 shares of common stock at an exercise price of \$4.78 per share, resulting in net proceeds to us, after the deduction of fees and commissions, of \$25.8 million.

Focus for 2006

Our primary focus for 2006 will be on the conduct of our Amoxicillin PULSYS Phase III clinical trial for adults and adolescents and, if we receive FDA approval of our Keflex line extension products, the commercial launch of these products in the second half of 2006. We will also continue clinical development of a once-daily version of Keflex PULSYS.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, fair valuation of stock related to stock-based compensation and income taxes. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenue for the sale of pharmaceutical products and for payments received under collaboration agreements for licensing, milestones, and reimbursement of development costs.

Product Sales. Revenue from product sales, net of estimated provisions, is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectibility is reasonably assured. Our customers consist primarily of large pharmaceutical wholesalers who sell directly into the retail channel. Provisions for sales discounts, and estimates for chargebacks, rebates, and product returns are established as a reduction of product sales revenue at the time revenues are recognized, based on historical experience adjusted to reflect known changes in the factors that impact these reserves. These revenue reductions are generally reflected either as a direct reduction to accounts receivable through an allowance, or as an addition to accrued expenses for estimated returns or if the payment is due to a party other than the wholesaler.

Chargebacks and rebates. These are based on the difference between the prices at which we sell our products to wholesalers and the sales price ultimately paid under fixed price contracts by third party payers, including governmental agencies. We record an estimate at the time of sale to the wholesaler of the amount to be charged back to us or rebated to the end user. We have recorded reserves for chargebacks and rebates based upon various factors, including current contract prices, historical trends, and our future expectations. The amount of actual chargebacks and rebates claimed could be either higher or lower than the amounts we accrued. Changes in our estimates would be recorded in the income statement in the period of the change.

Product returns. In the pharmaceutical industry, customers are normally granted the right to return product for a refund if the product has not been used prior to its expiration date, which for our Keflex products is typically three years from the date of manufacture for capsules, and two years for oral suspension products. Our return policy typically allows product returns for products within an eighteen-month window from six months prior to the expiration date and up to twelve months after the expiration date. We estimate the level of sales which will ultimately be returned pursuant to our return policy, and record a related reserve at the time of sale. These amounts are deducted from our gross sales to determine our net revenues. Our estimates take into consideration historical returns of our products and our future expectations. We periodically review the reserves established for returns and adjust them based on actual experience. The amount of actual product return could be either higher or lower than the amounts we accrued. Changes in our estimates would be recorded in the income statement in the period of the change. If we over or under estimate the quantity of product which will ultimately be returned, there may be a material impact to our financial statements.

Contract Revenue. We use the milestone payment method of revenue recognition when all milestones in respect of payments to be received under contractual arrangements are determined to be substantive, at-risk and the culmination of an earnings process. Substantive milestones are payments that are conditioned upon events requiring substantive effort, when the amounts of the milestones are reasonable relative to the time, effort and risk involved in achieving them and when the milestones are reasonable relative to each other and the amount of any up-front payment. If these criteria are not met, the timing of the recognition of revenue from the milestone payment may vary. Up-front payments are recorded as deferred revenue. We estimate the length of the remaining development period and amortize an up-front payment over that development period.

Reimbursement of Development Costs. We record revenue for reimbursement of development costs as the actual costs to perform the work are incurred. We are required to use judgment in recognizing reimbursement revenue in cases where the agreement provides for funding to us that is not dependent on actual costs we incur within a specific fiscal period. For our collaboration with Par Pharmaceutical for Amoxicillin PULSYS, for example, we were entitled to quarterly payments in pre-established amounts that funded our development work. Our policy is to limit revenue recognized to the minimum amounts expected under a specific collaboration agreement and to exclude amounts contingent on future events, such as successful commercialization and future profit-sharing, and amounts that are contingently refundable. Revenue recognized is limited to cumulative amounts under each contract such that, at any time, if a termination of the agreement were to occur, revenue previously recognized would not need to be reversed. Cash received in excess of revenue recognized is recorded as deferred revenue, with the deferred revenue recognized as revenue at the time future events occur that remove the contingencies.

Inventories

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out method. Inventory consists of Keflex finished capsules and finished oral suspension powder. We purchase our Keflex products from third-party manufacturers only at the completion of the manufacturing process, and accordingly have no raw material or work-in-process inventories. At least on a quarterly basis, we review our inventory levels and write down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value or is in excess of expected requirements. During 2005, we recorded an inventory reserve provision of approximately \$154,000 to cost of product sales related to slow-moving and obsolete inventory.

Intangible Assets

Acquired Intangible Assets. We acquired the U.S. rights to the Keflex brand of cephalexin in 2004. We may acquire additional pharmaceutical products in the future that include license agreements, product rights and other identifiable intangible assets. When intangible assets are acquired, we review and identify the individual intangible assets acquired and record them based on relative fair values. Each identifiable intangible asset is then reviewed to determine if it has a definite life or indefinite life, and definite-lived intangible assets are amortized over their estimated useful lives.

Impairment. We assess the impairment of our identifiable definite-lived intangible assets on at least an annual basis or when events or changes in circumstances indicate that the carrying value may not be recoverable. Some factors we consider important which could trigger an impairment review include significant underperformance compared to historical or projected future operating results, significant changes in our use of the acquired assets or the strategy for our overall business, or significant negative industry or economic trends. If we determine that the carrying value of intangible assets may not be recoverable based upon the existence of one or more of these factors, we first perform an assessment of the asset's recoverability based on expected undiscounted future net cash flow, and if the amount is less than the asset's value, we measure any impairment based on a projected discounted cash flow method using a discount rate determined by our management to be commensurate with the risk inherent in our current business model.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses for services performed and liabilities incurred. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued expenses for services include professional service fees, such as lawyers and accountants, contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in conjunction with clinical trials, and fees paid to contract manufacturers in conjunction with the production of clinical materials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often judgmental. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles. We also make estimates for other liabilities incurred, including health insurance costs for our employees. We are self-insured for claims made under our health insurance program and record an estimate at the end of a period for claims not yet reported. Our risk exposure is limited, as claims over a maximum amount are covered by an aggregate stop loss insurance policy.

Stock-Based Compensation

We have elected to follow APB Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting

method provided for under SFAS No. 123, *"Accounting for Stock-Based Compensation."* In the notes to our financial statements we provide pro forma disclosures in accordance with SFAS No. 148 and related pronouncements. We account for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS No. 123 and EITF Issue No. 96-18. The factors which are most likely to affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. Since the Company's initial public offering in October 2003, we have used the quoted market price of our common stock as the fair value, and we have established an estimate for volatility by considering the volatility of the stock of other comparable public companies. We expect to adopt SFAS 123R, "Share-Based Payment," in the first quarter of 2006.

Income Taxes

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have not recorded any tax provision or benefit for the years ended December 31, 2005, 2004 and 2003. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry forwards cannot presently be sufficiently assured. At December 31, 2005 and 2004, we had federal and state net operating loss carryforwards of approximately \$78.3 million and \$51.9 million, respectively, available to reduce future taxable income, which will begin to expire in 2020. Under the provisions of Section 382 of the Internal Revenue Code, certain substantial changes in our ownership may result in a limitation on the amount of net operating loss and research and experimentation tax credit carry forwards which can be used in future years. During 2005 and prior years, we may have experienced such ownership changes. When we complete the necessary studies, the amount of net operating loss carryovers may be reduced. However, since the valuation allowance fully reserves for all available carryovers, the effect of the reduction would be offset by a reduction in the valuation allowance. Thus, the resolution of this matter would have no effect on our reported assets, liabilities, revenues and expenses for the periods presented.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS 123R, *"Share-Based Payment,"* a revision of SFAS 123, *"Accounting for Stock-based Compensation."* SFAS 123R requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use APB 25's intrinsic value method of accounting for share-based payments. Accordingly, we plan to begin recognizing the expense associated with our share-based payments, as determined using a fair value-based method, in our statement of operations beginning on January 1, 2006. Adoption of the expense provisions of SFAS 123R is expected to have a material, noncash impact on our results of operations. The standard allows alternative transition methods for public companies. We expect to adopt the modified prospective application method as our transition method. Under this method, prior periods will not be restated. Compensation cost for the unvested portion of awards that are outstanding as of January 1, 2006 will be recognized as the requisite service is rendered on or after the effective date. The compensation cost for the unvested portion of those earlier awards will be based on the fair value at date of grant as previously calculated in our pro forma disclosure under SFAS 123, net of estimated forfeitures.

In February 2005, the EITF added to its agenda Issue No. 05-4, *"The Effect of a Liquidated Damages Clause on a Freestanding Financial Instrument Subject to EITF Issue No. 00-19, 'Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock.'"* The issue addresses liquidated damages provisions associated with registration rights agreements and the diversity in practice that exists in accounting for such provisions. In June 2005 and September 2005, the EITF discussed the Issue but did not reach a

consensus. Further deliberations by the EITF have been postponed until the FASB addresses whether a registration rights agreement is a derivative. The Company is monitoring the progress of the FASB and EITF on this Issue.

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections — a Replacement of APB Opinion No. 20 and FASB Statement No. 3." SFAS 154 generally requires retrospective application to prior periods' financial statements of voluntary changes in accounting principles. Under the prior rules, changes in accounting principles were generally recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. This statement does not change the previous requirements for reporting the correction of an error in previously issued financial statements, change in accounting estimate, or justification of a change in accounting principle on the basis of preferability. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 31, 2005. Adoption of the provisions of this statement is not expected to have a material effect on our results of operations or financial position.

In November 2005, the FASB Staff issued FASB Staff Position ("FSP") FAS 115-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." FSP FAS 115-1 addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. It also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP is effective for reporting periods beginning after December 15, 2005. FSP FAS 115-1 is not expected to have a material effect on our financial statements.

Research and Development Expenses

We expect our research and development expenses to be significant we continue to develop our product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers in conjunction with independently monitoring our clinical trials and acquiring and evaluating data in conjunction with our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop our products, and costs of facilities. We expense research and development costs as incurred. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates and proprietary technologies.

The following table summarizes research and development expense for our product development initiatives for the fiscal years ended December 31, 2005, 2004 and 2003. See "Our Product Pipeline" above for our current priority product candidates.

	Year Ended December 31,			Total Expense Incurred from Inception (January 1, 2000) to December 31, 2005	Clinical Development Phase
	2005	2004	2003		
Direct Project Costs(1)					
Amoxicillin(2)	\$24,294,000	\$15,961,000	\$ 4,890,000	\$ 48,130,000	Phase III
Keflex and Cephalexin PULSYS	5,360,000	222,000	—	5,582,000	Phase I
Generic Clarithromycin(3)	79,000	5,480,000	5,975,000	15,579,000	Suspended
Other Product Candidates	1,289,000	4,108,000	2,600,000	15,245,000	Preclinical
Total Direct Project Costs	31,022,000	25,771,000	13,465,000	84,536,000	
Indirect Project Costs(1) Facility	3,603,000	2,954,000	1,113,000	8,965,000	
Depreciation	2,610,000	1,928,000	664,000	5,878,000	
Other Indirect Overhead	2,494,000	2,990,000	1,353,000	7,871,000	
Total Indirect Project Costs	8,707,000	7,872,000	3,130,000	22,714,000	
Total Research & Development Expense	<u>\$39,729,000</u>	<u>\$33,643,000</u>	<u>\$16,595,000</u>	<u>\$107,250,000</u>	

- (1) Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record direct costs, including personnel costs and related benefits and stock-based compensation, on a project-by-project basis. We record indirect costs that support a number of our research and development activities in the aggregate.
- (2) We currently have an adult and adolescent amoxicillin formulation in a Phase III clinical trial, which commenced enrollment in November 2005. We previously conducted Phase III clinical trials for the adolescent/adult formulation which commenced October 15, 2004 and for the pediatric formulation which commenced on January 5, 2005. These two previous Phase III trials failed to achieve their desired microbiological and clinical endpoints. See "Amoxicillin PULSYS Clinical Results" above. We previously had an agreement under which Par Pharmaceutical was responsible for funding the anticipated future development costs of this product. See "Termination of Our Collaboration with Par Pharmaceutical for Amoxicillin PULSYS" above.
- (3) We have discontinued development efforts for this product. See "Our Collaboration with Par Pharmaceutical for Generic Clarithromycin" above.

Net Losses

We have a limited history of operations. We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including payments made or received pursuant to licensing or collaboration agreements, progress of our research and development efforts, approval and commercial launch of new products, and the timing and outcome of regulatory approvals. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of December 31, 2005, we had an accumulated deficit of approximately \$111.1 million. We anticipate incurring additional annual losses, perhaps at higher levels, for the foreseeable future.

Results of Operations

Fiscal Year Ended December 31, 2005 Compared to Fiscal Year Ended December 31, 2004

Revenues. We recorded revenues of \$16.8 million during the fiscal year ended December 31, 2005 compared to \$11.4 million during the fiscal year ended December 31, 2004, as follows:

	<u>Year Ended December 31,</u>	
	<u>2005</u>	<u>2004</u>
Keflex product sales, net	\$ 4,809,000	\$ 2,397,000
Contract revenue — amortization of upfront licensing fees:		
GSK	—	1,146,000
GSK — acceleration upon termination	—	3,229,000
Par — amoxicillin	797,000	972,000
Par — amoxicillin — acceleration upon termination	3,231,000	—
Reimbursement of development costs:		
Par — amoxicillin	5,636,000	3,614,000
Par — amoxicillin — acceleration upon termination	<u>2,375,000</u>	<u>—</u>
Total	<u>\$16,848,000</u>	<u>\$11,358,000</u>

Product sales of Keflex commenced in July 2004, subsequent to the purchase of the brand rights in the U.S. market from Eli Lilly; therefore, results for 2004 reflect six months of sales compared to 12 months in 2005.

Revenues recognized in 2005 for amortization of upfront licensing fees include the amortization of a \$5.0 million upfront payment received from Par Pharmaceutical in 2004, of which the remainder of \$3.2 million was recognized in 2005 due to the termination of the collaboration agreement. Revenue for amortization of upfront licensing fees from GlaxoSmithKline in 2004 represented amortization of the \$5.0 million upfront payment

received from GSK in May, 2004, with no comparable amount in 2005 due to the termination of the GSK collaboration in December 2004.

Reimbursement of development costs under the Par amoxicillin PULSYS collaboration agreement was recognized as revenue based on the related costs incurred. As a result of the termination of the collaboration on August 3, 2005, we accelerated the revenue recognition of \$2.4 million, which represented the remaining deferred revenue balance in excess of the amount retained for future contingent liability to Par.

Cost of Product Sales. Cost of product sales represents the purchase cost of the Keflex products sold, together with royalties due on the sale of certain Keflex products. Cost of product sales was \$0.6 million in 2005 and \$0.2 million in 2004.

Research and Development Expenses. Research and development expenses increased \$6.1 million, or 18%, to \$39.7 million for the fiscal year ended December 31, 2005 from \$33.6 million for the fiscal year ended December 31, 2004. Research and development expenses consist of direct costs which include salaries and related costs of research and development personnel, and the costs of consultants, materials and supplies associated with research and development projects, as well as clinical studies. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

The following table discloses the components of research and development expenses reflecting our project expenses.

<u>Research and Development Expenses</u>	<u>Year Ended December 31,</u>	
	<u>2005</u>	<u>2004</u>
Direct project costs:		
Personnel, benefits and related costs	\$10,716,000	\$ 9,522,000
Stock-based compensation.	160,000	1,173,000
Consultants, supplies, materials and other direct costs	7,912,000	8,595,000
Clinical studies	<u>12,234,000</u>	<u>6,481,000</u>
Total direct costs	31,022,000	25,771,000
Indirect project costs	<u>8,707,000</u>	<u>7,872,000</u>
Total	<u>\$39,729,000</u>	<u>\$33,643,000</u>

Personnel, benefits and related costs increased \$1.2 million in 2005 primarily due to severance charges of \$2.9 million versus \$0.4 million in 2004, partly offset by a benefit of \$1.3 million due to lower staffing levels throughout 2005 attributable to reductions in staff in November 2004 and July 2005. Stock-based compensation costs declined \$1.0 million, of which \$0.9 million results from use of the FIN 28 accelerated method of amortization, and the remaining decrease is due to cancellation of options for which expense had previously been recognized.

Contract R&D, consultants, materials and other costs decreased \$0.7 million, due to a reduction in costs of \$1.9 million on the generic clarithromycin project that was discontinued in 2004, and reductions in other projects of \$1.9 million. Partly offsetting the decreases were increased costs of \$1.8 million for Keflex product development, \$1.0 million for pediatric and adult amoxicillin trials, and other projects of \$0.3 million. Clinical trials expense increased \$5.8 million overall, due to \$7.6 million increased expense in 2005 for Phase III clinical trials of adult and pediatric amoxicillin, partly offset by lower expenses for generic clarithromycin of \$1.3 million and other projects of \$0.5 million.

Indirect project costs also increased by \$0.8 million, primarily due to an increase in facility-related costs of \$0.8 million and equipment depreciation of \$0.7 million, resulting from the acquisition of product manufacturing equipment used to produce amoxicillin for clinical trials, offset by changes in all other indirect expenses of \$0.7 million.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased \$1.7 million, or 14%, to \$10.5 million for the year ended December 31, 2005 from \$12.2 million for the year ended December 31, 2004.

	Year Ended December 31,	
	2005	2004
Salaries, benefits and related costs	\$ 3,387,000	\$ 2,667,000
Stock-based compensation	376,000	2,480,000
Legal and consulting expenses	1,342,000	2,694,000
Other expenses	5,410,000	4,378,000
Total	<u>\$10,515,000</u>	<u>\$12,219,000</u>

Salaries, benefits and related costs in 2005 increased \$0.7 million, which was primarily attributable to severance costs of \$1.1 million. Stock-based compensation costs decreased a total of \$2.1 million, due to a decrease of \$1.1 million attributable to the use of an accelerated method of amortization to recognize employee-based option expense recognized under APB 25, a decrease of \$0.5 million due to reversal of prior period expense for the forfeiture of options that resulted from the termination of employees in 2005, and a decrease of \$0.5 million due to a one-time charge in 2004 for stock-based compensation related to retirement of a director.

Legal and consulting costs decreased \$1.4 million due primarily to a higher level of legal activity in 2004 in support of collaboration agreement negotiations. Other expenses increased \$1.0 million, which included amortization of the Keflex intangible assets of \$0.6 million, and increased facilities costs of \$0.4 million.

Net Interest Income (Expense). Net interest income was \$1.0 million for the year ended December 31, 2005 compared to net interest income of \$0.7 million for the year ended December 31, 2004. The increase is primarily attributable to higher short term interest rates in 2005 versus 2004.

	Year Ended December 31,	
	2005	2004
Interest income	\$1,075,000	\$ 794,000
Interest expense	<u>(121,000)</u>	<u>(125,000)</u>
Total, net.	<u>\$ 954,000</u>	<u>\$ 669,000</u>

Fiscal Year Ended December 31, 2004 Compared to Fiscal Year Ended December 31, 2003

Revenues. We recorded revenues of \$11.4 million during the fiscal year ended December 31, 2004 compared to \$3.6 million during the fiscal year ended December 31, 2003, as follows:

	<u>Year Ended December 31,</u>	
	<u>2004</u>	<u>2003</u>
Keflex product sales, net	\$ 2,397,000	\$ —
Contract revenue:		
Achievement of GSK project milestone	—	3,000,000
Amortization of upfront GSK payment	1,146,000	625,000
Recognition of remaining GSK payment upon termination	3,229,000	—
Amortization of upfront Par payment	972,000	—
Reimbursement of development costs — Par amoxicillin	3,614,000	—
Total	<u>\$11,358,000</u>	<u>\$3,625,000</u>

Product sales of Keflex commenced in July 2004, subsequent to the purchase of the brand rights in the U.S. market from Eli Lilly. There were no product sales in 2003.

Revenues recognized in 2004 and 2003 from the amortization of upfront licensing fees include the amortization of a \$5.0 million upfront payment received from GlaxoSmithKline (GSK) in July 2003, of which the unamortized portion of \$3.2 million was recognized in 2004 due to the termination of the collaboration agreement, and the amortization of a \$5.0 million upfront payment received from Par Pharmaceutical in May 2004, which was being amortized into revenue on a straight-line basis over a 36-month period.

Reimbursement of development costs revenue of \$3.6 million related to the Par amoxicillin agreement was recognized based on the related costs incurred.

Cost of Product Sales. Cost of product sales represents the purchase cost of the Keflex products sold. Cost of product sales was \$170,000 in 2004. There were no product sales in 2003.

Research and Development Expenses. Research and development expenses increased \$17.0 million, or 103%, to \$33.6 million for the fiscal year ended December 31, 2004 from \$16.6 million for the fiscal year ended December 31, 2003. Research and development expenses consist of direct costs which include salaries and related costs of research and development personnel, and the costs of consultants, materials and supplies associated with research and development projects, as well as clinical studies. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

The following table shows the aggregate changes in research and development expenses reflecting all of our project expenses.

<u>Research and Development Expenses</u>	<u>Year Ended December 31,</u>	
	<u>2004</u>	<u>2003</u>
Direct project costs:		
Personnel, benefits and related costs	\$ 9,522,000	\$ 5,866,000
Stock-based compensation	1,173,000	1,903,000
Consultants, supplies, materials and other direct costs	8,595,000	3,737,000
Clinical studies	6,481,000	1,959,000
Total direct costs	25,771,000	13,465,000
Indirect project costs	7,872,000	3,130,000
Total	<u>\$33,643,000</u>	<u>\$16,595,000</u>

Direct costs increased \$12.3 million primarily as a result of increases of \$11.1 million relating to the development of our pulsatile amoxicillin product candidate, plus increases of an aggregate of \$2.4 million relating

to the evaluation of new preclinical product candidates, partially offset by decreases of an aggregate of \$1.4 million relating to the development of our pulsatile clarithromycin and generic clarithromycin product candidates.

Increased project staffing levels in 2004 versus 2003 resulted in an increase of \$3.7 million related to personnel, benefits and related costs. Contract research and development, consulting, materials and other direct costs increased \$4.9 million in preparation for our clinical trials, and clinical trials expense increased \$4.5 million from 2003 as we initiated two Phase III studies in 2004 (adult and pediatric amoxicillin PULSYS) as well as conducted 13 Phase I/II studies compared to nine Phase I/II studies in 2003.

Indirect project costs also increased by \$4.7 million, primarily due to an increase in facility-related costs of \$1.8 million, depreciation of \$1.3 million, and overhead of \$1.6 million due to increased insurance, Scientific Advisory Board expenses, and other expenses.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased \$5.8 million, or 90%, to \$12.2 million for the fiscal year ended December 31, 2004 from \$6.4 million for the fiscal year ended December 31, 2003.

	Year Ended December 31,	
	2004	2003
Salaries, benefits and related costs	\$ 2,667,000	\$1,847,000
Stock-based compensation	2,480,000	1,538,000
Legal and consulting expenses	2,694,000	1,773,000
Other expenses	4,378,000	1,269,000
Total	<u>\$12,219,000</u>	<u>\$6,427,000</u>

Selling, general and administrative expenses consist of salaries and related costs for executive and other administrative personnel, as well as professional fees and facility costs. Salaries, benefits and related costs for personnel increased \$0.8 million in 2004 due to higher compensation and benefits expenses related to new hires. Approximately \$0.9 million of the total \$5.8 million increase in general and administrative expenses is attributable to increased stock-based compensation charges, primarily due to the effect of certain 2003 grants being amortized for a full year in 2004. Legal and consulting costs increased \$0.9 million in 2004 due to increased support activities attributable to the Company's first full year of being a publicly-traded corporation, assistance in business development activities, litigation support and Sarbanes-Oxley compliance. Other expenses increased \$3.1 million, principally due to higher costs for building and equipment operating expenses and depreciation of \$0.5 million, amortization of \$0.6 million of Keflex intangibles, increased audit fees and investor communications costs of \$0.3 million related to the Company's first full-year status as a public company, and increased business development marketing costs of \$0.7 million related to identification and development of new market opportunities, including Keflex brand enhancement.

Net Interest Income (Expense). Net interest income was \$669,000 for the fiscal year ended December 31, 2004 compared to net interest expense of \$1.6 million for the fiscal year ended December 31, 2003.

	Year Ended December 31,	
	2004	2003
Interest income	\$ 794,000	\$ 254,000
Interest expense, net of interest capitalized	(125,000)	(165,000)
Beneficial conversion feature — deemed interest expense	—	(1,667,000)
Total, net	<u>\$ 669,000</u>	<u>\$(1,578,000)</u>

The increase in net interest income in 2004 of \$2.2 million is primarily due to the beneficial conversion feature of deemed interest expense of \$1.7 million incurred in 2003 (no similar item in 2004), plus increased interest income in 2004 of \$540,000 resulting from the Company's investment in marketable securities subsequent to its initial public offering of common stock in the second half of 2003. The deemed interest expense related to the

beneficial conversion feature was a one-time charge that related to the issuance of the Company's convertible notes in March 2003 at a favorable conversion ratio for the noteholders.

Interest expense (net of capitalized interest) decreased \$40,000 compared to the prior year. The Company has paid down in 2004 older fixed rate borrowings that were at higher interest rates than its newer, variable rate borrowings.

Liquidity and Capital Resources

We have funded our operations principally with the proceeds of \$54.5 million from a series of five preferred stock offerings and one issue of convertible notes over the period 2000 through 2003, the net proceeds of \$54.3 million from our initial public offering in October 2003, and a private placement of common stock for net proceeds of \$25.8 million in April 2005. In addition, we have received funding of \$8.0 million and \$28.25 million from GlaxoSmithKline and Par Pharmaceutical, respectively, as a result of collaboration agreements for the development of new products. Since July 2004, we have also received cash from sales of our Keflex products. We also received a \$1.0 million advance payment in 2005 from a potential buyer of our Keflex brand, which we retained as the sale was not completed.

Cash and Marketable Securities

At December 31, 2005, unrestricted cash, cash equivalents and marketable securities were \$29.0 million compared to \$30.1 million at December 31, 2004.

	As of December 31,	
	2005	2004
Cash and cash equivalents	\$18,117,000	\$10,396,000
Marketable securities	11,314,000	19,656,000
Total	<u>\$29,431,000</u>	<u>\$30,052,000</u>

Restricted cash at December 31, 2005 of approximately \$0.4 million will become unrestricted during 2006 and provide additional liquidity.

Our cash and cash equivalents are highly-liquid investments with a maturity of 90 days or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Our marketable securities are also highly-liquid investments and are classified as available-for-sale, as they can be utilized for current operations. The Company's investment policy requires the selection of high-quality issuers, with bond ratings of AAA to A1+/P1. The Company's objective is to maintain its investment portfolio at an average duration of approximately one year.

Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances.

Cash Flow

The following table summarizes our sources and uses of cash and cash equivalents for fiscal years ending December 31, 2005, 2004, and 2003.

	Year Ended December 31,		
	2005	2004	2003
Net cash used in operating activities	\$(24,890,000)	\$(15,487,000)	\$(11,084,000)
Net cash provided by (used in) investing activities ..	7,676,000	(11,721,000)	(36,413,000)
Net cash provided by financing activities	<u>24,935,000</u>	<u>153,000</u>	<u>80,887,000</u>
Net increase (decrease) in cash and cash equivalents	<u>\$ 7,721,000</u>	<u>\$(27,055,000)</u>	<u>\$ 33,390,000</u>

Operating Activities

Net cash used in operating activities for the three years ended December 31, 2005 is presented in the following table, which displays cash received and cash disbursed by major element.

<u>Operating Activities</u>	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Cash receipts:			
Cash received from product sales	\$ 5,159,000	\$ 2,230,000	\$ —
Cash received from collaboration partners	14,250,000	17,000,000	5,000,000
Interest income received and other	<u>1,622,000</u>	<u>2,185,000</u>	<u>581,000</u>
Total cash receipts	<u>21,031,000</u>	<u>21,415,000</u>	<u>5,581,000</u>
Cash disbursements:			
Cash paid for employee compensation and benefits	11,432,000	10,401,000	6,826,000
Cash paid to vendors, suppliers, and other	<u>34,489,000</u>	<u>26,501,000</u>	<u>9,839,000</u>
Total cash disbursements	<u>45,921,000</u>	<u>36,902,000</u>	<u>16,665,000</u>
Net cash used in operating activities	<u>\$(24,890,000)</u>	<u>\$(15,487,000)</u>	<u>\$(11,084,000)</u>

Cash received from product sales in 2005 of \$5.2 million significantly exceeded product sales cash receipts in 2004 of \$2.2 million, as the 2004 amount reflects only about a half year of activity. Cash received from collaboration partners relates to our previous collaboration agreements with Par Pharmaceutical for amoxicillin PULSYS and with GlaxoSmithKline for amoxicillin/clavulanate development. We received \$14.25 million and \$14.0 million in 2005 and 2004, respectively, from Par and \$3.0 million and \$5.0 million in 2004 and 2003, respectively, from GSK. The increase in cash disbursements from 2003 to 2005 reflects the growth in the Company's average headcount and the significant costs involved in the Company's Phase III clinical trials in 2004 and 2005.

Investing Activities

Net cash used in investing activities for the three years ended December 31, 2005 is presented in the following table, which displays cash received and cash disbursed by major element.

<u>Investing Activities</u>	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Cash receipts:			
Sale of marketable securities, net of purchases	\$8,176,000	\$ 6,582,000	\$ —
Advance payment received for potential sale of Keflex	1,000,000	—	—
Sale of fixed assets, restricted cash and other	<u>423,000</u>	<u>—</u>	<u>830,000</u>
Total cash receipts	<u>9,599,000</u>	<u>6,582,000</u>	<u>830,000</u>
Cash disbursements:			
Purchase of marketable securities	—	—	27,858,000
Purchase of Keflex brand rights	—	11,206,000	—
Property and equipment purchases and deposits	1,923,000	6,960,000	9,047,000
Change in restricted cash and other	<u>—</u>	<u>137,000</u>	<u>338,000</u>
Total cash disbursements	<u>1,923,000</u>	<u>18,303,000</u>	<u>37,243,000</u>
Net cash used in investing activities	<u>\$7,676,000</u>	<u>\$(11,721,000)</u>	<u>\$(36,413,000)</u>

The most significant investing activities in 2005 included net purchases and sales of marketable securities of \$8.2 million, receipt of a \$1.0 million advance payment pursuant to the potential sale of Keflex assets (which we

retained, as the agreement-in-principle expired without the sale of the business), and purchases of and deposits on property and equipment of \$1.9 million.

Net cash used in investing activities during the year ended December 31, 2004 was \$11.7 million. The most significant investing activities included the acquisition of Keflex intangibles for \$11.2 million, and purchases of and deposits on property and equipment of \$7.0 million. Net purchases and sales of marketable securities provided \$6.6 million during the period.

Net cash used in investing activities during fiscal 2003 was \$36.4 million. The Company invested \$27.9 million of its IPO proceeds in marketable securities, representing securities with maturities exceeding 90 days. The Company also spent \$9.0 million (excluding \$1.6 million of accrued construction costs) on the acquisition of property and equipment, primarily for the fit-out of its new corporate, research and development facility in Germantown, Maryland. An additional \$338,000 of cash was required by the Company's equipment financing terms to be placed in financial institutions on a restricted basis as additional loan collateral. Partially offsetting these cash outflows was the receipt of \$830,000 in cash as part of the tenant improvement allowance for our corporate, research and development facility; this amount will be amortized as a reduction in rent expense over the term of the lease.

Financing Activities

Net cash provided by financing activities for the three years ended December 31, 2005 is presented in the following table, which displays cash received and cash disbursed by major element.

<u>Financing Activities</u>	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Cash receipts:			
Cash received from private placement	\$25,844,000	\$ —	\$ —
Cash received from lines of credit	—	1,390,000	1,346,000
Cash received from initial public offering	—	—	54,312,000
Cash received from preferred stock and notes	—	—	25,775,000
Cash received from exercise of stock options	101,000	16,000	91,000
Total cash receipts	<u>25,945,000</u>	<u>1,406,000</u>	<u>81,524,000</u>
Cash disbursements:			
Cash paid for debt payments	1,010,000	1,253,000	637,000
Total cash disbursements	<u>1,010,000</u>	<u>1,253,000</u>	<u>637,000</u>
Net cash provided by financing activities	<u>\$24,935,000</u>	<u>\$ 153,000</u>	<u>\$80,887,000</u>

The major financing activity in 2005 was the private placement of common stock, which provided \$25.8 million net of issuance costs. Additionally, repayments on lines of credit totaled \$1.0 million during the period.

Net cash provided by financing activities in 2004 was \$0.2 million. The major financing activities included loan draws of \$1.4 million for equipment financing in connection with the fit-out of the Company's new corporate, research and development facility and repayments of \$1.2 million on the Company's existing borrowings.

Net cash from financing activities for fiscal 2003 was \$80.9 million. The major financing activities included \$5.0 million from the issue of convertible notes in March 2003, \$20.8 million from the closing of the Series E preferred stock financing round in July 2003, and \$54.3 million from the closing of Company's initial public offering of its common stock in October 2003. The Company also obtained \$1.3 million from draws under its lines of credit for equipment financing.

Borrowings

We are a party to four credit facilities for an aggregate amount of \$5.9 million used to finance the purchase of equipment and to one loan agreement for \$75,000 with a local government development fund. The credit facilities

have no amounts available for new borrowings. Of the total \$5.9 million amount, \$1.6 million was outstanding as of December 31, 2005, as summarized in the following table:

<u>Debt Obligations</u>	<u>As of December 31, 2005</u>		
	<u>Interest Rates</u>	<u>Amount Outstanding</u>	<u>Remaining Amount Available</u>
Fixed rate borrowings	5.00% — 11.62%	\$ 190,000	\$—
Variable rate borrowings	LIBOR or Fixed Cost of Funds plus 250 — 280 basis points	1,377,000	—
Totals		<u>\$1,567,000</u>	<u>\$—</u>

We do not currently hedge variable rate borrowings.

Stock Issuances

In April 2005, we completed a private placement of 6,846,735 shares of our common stock at a price of \$3.98 per share and warrants to purchase a total of 2,396,357 shares of common stock at an exercise price of \$4.78 per share, resulting in net proceeds, after commissions and expenses, of \$25.8 million. The warrants are exercisable for five years.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2005 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

<u>Contractual Obligations (1), (2)</u>	<u>Payments Due by Period</u>						
	<u>Total</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>After 2010</u>
			<u>(In thousands)</u>				
Short and long-term debt (includes interest)	\$ 1,636	\$ 949	\$ 636	\$ 51	\$ —	\$ —	\$ —
Minimum purchase commitments (3)	1,239	1,239	—	—	—	—	—
Operating lease obligations	16,033	2,126	2,080	2,139	2,156	2,214	5,318
Total contractual cash obligations	<u>\$18,908</u>	<u>\$4,314</u>	<u>\$2,716</u>	<u>\$2,190</u>	<u>\$2,156</u>	<u>\$2,214</u>	<u>\$5,318</u>
Other commercial commitments(4)	<u>\$ 4,545</u>	<u>\$4,545</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

- (1) This table does not include potential royalty payments, at a rate of 10% of sales value, to Eli Lilly and Company, which may be due on product line extensions of Keflex. Any such royalties cannot be estimated at this time.
- (2) This table does not include a contingent liability to Par Pharmaceutical under our amoxicillin development and commercialization agreement that was terminated by Par in August 2005. Under certain circumstances, the termination clauses of the agreement may entitle Par to receive a share of future net profits, if any, up to one-half of Par's total \$23.25 million investment in the development of certain amoxicillin PULSYS products, should a product covered by the agreement be successfully commercialized. Accordingly, we retained \$11.625 million of deferred revenue in recognition of this contingent liability to Par.
- (3) We have entered into a manufacturing agreement with Ceph International for the manufacturing of our Keflex products. This agreement contains a provision for minimum purchase requirements.
- (4) We have entered into other contractual agreements in connection with developing our products and technology and to perform clinical trials. This amount represents the remaining contractual amount due for our on-going Phase III clinical trial. Although the contract could be cancelled by us, in which case we would be liable to the

vendor for work performed to the date of cancellation, it is our intent to complete the clinical trial at the remaining cost of approximately \$4.5 million.

In addition to the contractual obligations in the above table, the Company may incur funding liabilities for obligations which it enters into on a discretionary basis. These discretionary obligations could include additional facilities or equipment, investments in new technologies or products, acquisitions, funding of clinical trials, or similar events. As of December 31, 2005, we are not committed to fund any further pre-production development work at the Clonmel facility; however, should our Amoxicillin PULSYS Phase III trial be successful, our intention would be to fund approximately \$2.8 million of additional development work at Clonmel, primarily in late 2006 and early 2007, to prepare for commercial production of Amoxicillin PULSYS.

During fiscal 2005 we spent approximately \$1.4 million for capital expenditures, primarily for equipment purchased for use at third-party manufacturing facilities, as well as for use in our research and development facility in Germantown, Maryland.

Off-Balance Sheet Arrangements

We have not entered into any transactions, agreements or other contractual arrangements that meet the definition of off-balance sheet arrangements, with the exception of our private placement of common stock and warrants in April 2005. Warrants are instruments that meet the definition of a derivative under SFAS 133, although they qualify for the scope exception under paragraph 11 of SFAS 133. In the private placement, warrants were issued to purchase a total of 2,396,357 shares of common stock at an exercise price of \$4.78 per share.

Prospective Information

We expect to incur losses from operations for the foreseeable future. We expect to continue to incur substantial research and development expenses in 2006, including expenses related to preclinical testing and clinical trials. We expect that our selling and marketing expenses will increase in 2006, assuming FDA approval of our Keflex line extension products and commercial launch of the new products. If the launch is successful, we will collect cash on these incremental sales which would offset some or all of our increased selling and marketing expenses in 2006. We believe the Keflex line extension products have the potential to generate significant cash in excess of selling costs in 2007. We also expect a limited window of opportunity for these products, approximating 18 to 24 months, should generic pharmaceutical companies decide to compete with our line extension products.

Our future capital requirements will depend on a number of factors, including the continued progress of our research and development of product candidates, the timing and outcome of regulatory approvals, payments received or made under any future collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products, the availability of financing and our or our partners' success in developing markets for our product candidates.

After receiving the results in June and July 2005 of our unsuccessful pediatric and adult Phase III trials, we conducted an intensive analysis of the data with the intent to reach a conclusion regarding the future of our Amoxicillin PULSYS development program. We also considered how to maximize the future value of our Keflex franchise. Each of these outstanding matters has significant implications for our anticipated level of future spending and our capital available to fund future operations. In September 2005, we announced our decisions regarding these outstanding matters. We decided to continue our Amoxicillin PULSYS development program and to conduct a new Phase III clinical trial. We also decided to investigate the potential sale of the Keflex brand in order to increase our level of unrestricted cash on hand.

In July and September 2005, we reduced our workforce by approximately 38% as part of an initiative to reduce operating expenses. The cost reduction will enhance our ability to rely on our existing resources to fund our operations over the next year. We believe that our cash, cash equivalents and marketable securities of \$29.4 million on hand as of December 31, 2005, together with the effect of the reduction in our workforce in the third quarter of 2005 and product revenue collections in 2006 from sales of our currently-marketed Keflex products, provide us with enough capital resources to finance our ongoing operations, including our new Phase III clinical trial, until at least

the first quarter of 2007. We will continue to balance our pace of development with our funding position, and we anticipate the resources described above will be sufficient to fund our planned operating expenses, debt repayments and capital equipment requirements for at least the next 12 months, barring unforeseen developments. This forecast is a forward-looking statement that involves risks and uncertainties, and actual results could vary.

We have no unused credit facility or other committed sources of capital. To the extent our capital resources are insufficient to meet future capital requirements, we will need to raise additional capital, incur indebtedness, or consider the sale of company assets in order to fund our operations. There can be no assurance that additional debt or equity financing will be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts, effect changes to our facilities or personnel, or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently. Any future funding may dilute the ownership of our equity investors.

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995

Certain statements contained in "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements are based on our current intent, belief and expectations. These statements are not guarantees of future performance and are subject to certain risks and uncertainties that are difficult to predict. Actual results may differ materially from these forward-looking statements because of our unproven business model, our dependence on new technologies, the uncertainty and timing of clinical trials, our ability to develop and commercialize products, our dependence on collaborators for services and revenue, our substantial indebtedness and lease obligations, our changing requirements and costs associated with planned facilities, intense competition, the uncertainty of patent and intellectual property protection, our dependence on key management and key suppliers, the uncertainty of regulation of products, the impact of future alliances or transactions and other risks described in this filing and our other filings with the Securities and Exchange Commission. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. We undertake no obligation to update or revise the information contained in this announcement whether as a result of new information, future events or circumstances or otherwise.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities, and restricted cash that generally have maturities of less than one year. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash, cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments, but may increase the interest expense associated with our debt.

Our most liquid assets are cash, cash equivalents and marketable securities. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our intellectual property. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our balance sheet. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Item 8. *Financial Statements and Supplementary Data*

The information required by this item is set forth on pages F-1 to F-30.

Item 9. *Changes and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2005. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in this annual report on Form 10-K has been appropriately recorded, processed, summarized and reported. Based on that evaluation, our principal executive and principal financial officers have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting during the Quarter

Our management, including our principal executive and principal financial officers, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2005, and has concluded that there was no change that occurred during the quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Controls over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal controls over financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's system of internal controls over financial reporting was designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management, including the chief executive officer and chief financial officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2005. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Based on our assessment, management concluded that the Company maintained effective internal control over financial reporting as of December 31, 2005.

The Company's independent registered public accounting firm have issued an audit report on management's assessment of the Company's internal control over financial reporting. Their report appears on page F-2 and F-3.

Item 9B. *Other Information*

None.

PART III

Item 10. *Directors and Executive Officers of the Registrant*

We incorporate herein by reference the information concerning directors and executive officers in our Notice of Annual Stockholders' Meeting and Proxy Statement to be filed within 120 days after the end of our fiscal year (the "2006 Proxy Statement").

Item 11. *Executive Compensation*

We incorporate herein by reference the information concerning executive compensation to be contained in the 2006 Proxy Statement.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

We incorporate herein by reference the information concerning security ownership of certain beneficial owners and management to be contained in the 2006 Proxy Statement.

Item 13. *Certain Relationships and Related Transactions*

We incorporate herein by reference the information concerning certain relationships and related transactions to be contained in the 2006 Proxy Statement.

Item 14. *Principal Accounting Fees and Services*

We incorporate herein by reference the information concerning principal accounting fees and services to be contained in the 2006 Proxy Statement.

PART IV

Item 15. *Exhibits, Financial Statement Schedules, and Reports on Form 8-K*

(a) The following documents are filed as part of this Annual Report:

(1) Index to Financial Statements

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(2) Financial Statement Schedule

The following schedule is filed as part of this Form 10-K:

Exhibit II — Valuation and Qualifying Accounts for the Years Ended December 31, 2005, 2004, and 2003

(3) Exhibits

Exhibit No.

- 2.1^{(1)†+} Asset Purchase Agreement dated as of June 30, 2004, by and between the Registrant and Eli Lilly and Company
- 3.1⁽²⁾ Certificate of Incorporation
- 3.2⁽²⁾ Bylaws
- 4.1⁽²⁾ Specimen Stock Certificate
- 10.1⁽²⁾ Executive Employment Agreement between the Registrant and Edward M. Rudnic dated January 7, 2000
- 10.2⁽²⁾ Executive Employment Agreement between the Registrant and Sandra E. Wassink dated August 13, 2003
- 10.3⁽²⁾ Executive Employment Agreement between the Registrant and Beth A. Burnside dated August 13, 2003
- 10.4⁽²⁾ Executive Employment Agreement between the Registrant and Darren Buchwald dated September 1, 2003
- 10.5⁽³⁾ Executive Employment Agreement between the Registrant and Donald Treacy dated March 19, 2004
- 10.6 Executive Employment Agreement between the Registrant and Robert C. Low dated December 12, 2005
- 10.7⁽²⁾ Form of Indemnification Agreement
- 10.8⁽⁴⁾ Amended and Restated Stock Incentive Plan
- 10.9⁽²⁾ Form of Incentive Stock Option Agreement
- 10.10⁽²⁾ Form of Non-qualified Stock Option Agreement
- 10.11⁽²⁾ Form of Stock Restriction Agreement
- 10.12⁽⁵⁾ Employee Stock Purchase Plan
- 10.13⁽²⁾ Form of Employment Agreement on Ideas, Inventions and Confidential Information
- 10.14⁽²⁾ Construction Services Agreement between the Registrant and Barclay White Skanska, Inc. dated July 12, 2002
- 10.15⁽²⁾ Amendment No. 1 dated April 7, 2003 to Agreement between Owner and Construction Manager dated July 12, 2002 between the Registrant and Skanska USA Building, Inc. successor by merger to Barclay White Skanska, Inc.
- 10.16⁽²⁾ Standard Form of Agreement between Owner and Architect with Standard Form of Architect's Services between the Registrant and Gaudreau, Inc. dated July 8, 2002
- 10.17⁽²⁾ Lease Agreement between the Registrant and Seneca Meadows Corporate Center II LLC dated August 1, 2002
- 10.18⁽²⁾ Stock Purchase Pledge Agreement between the Registrant and Edward M. Rudnic dated October 15, 2001
- 10.19⁽²⁾ Form of Stock Purchase Promissory Note by Edward M. Rudnic dated October 15, 2001
- 10.20⁽²⁾ Amendment dated June 12, 2002 to Stock Purchase Pledge Agreement dated October 15, 2001 between the Registrant and Edward M. Rudnic
- 10.21⁽²⁾ Amendment dated July 30, 2003 to the Stock Purchase Pledge Agreement and Stock Restriction Agreement dated October 15, 2001, as amended, between the Registrant and Edward M. Rudnic

Exhibit No.

10.22 ⁽²⁾	Note Issuance Agreement between the Registrant and HealthCare Ventures VI, L.P., Rho Management Trust, I, Steven Ostrofsky, Private Equity Holdings L.L.C., Targeted Entrepreneurial Services, LLC and the DC 1998 NFA Trust FBO Lee Casty dated March 28, 2003
10.23 ⁽²⁾	Form of Convertible Promissory Note dated March 28, 2003
10.24 ⁽²⁾	Amendment to Secured Convertible Promissory Note dated June 23, 2003
10.25 ⁽²⁾	Fourth Amended and Restated Stockholders' Agreement
10.26 ⁽²⁾	Omnibus Addendum and Amendment to Series E Convertible Preferred Stock Purchase Agreement and Fourth Amended and Restated Stockholders' Agreement
10.27 ⁽²⁾	Consulting Agreement dated August 18, 2000 between the Registrant and Jenefir Isbister as amended
10.28 ⁽²⁾	Credit Agreement between the Registrant and Manufacturers and Traders Trust Company dated July 31, 2003
10.29 ⁽²⁾	Specific Security Agreement between the Registrant and Manufacturers and Traders Trust Company dated July 31, 2003
10.30 ⁽²⁾⁺	Development and License Agreement between the Registrant and GlaxoSmithKline dated July 18, 2003
10.31 ⁽²⁾⁺	Supply, Distribution and Marketing Agreement between the Registrant and Par Pharmaceutical, Inc. dated September 4, 2003
10.32 ⁽²⁾⁺	Manufacturing Agreement dated as of June 30, 2004, by and between the Registrant and Eli Lilly and Company
10.33 ⁽²⁾⁺	Transition Services Agreement dated as of June 30, 2004, by and between the Registrant and Eli Lilly and Company
10.34 ⁽⁵⁾⁺	Development and Commercialization Agreement between the Registrant and Par Pharmaceutical, Inc. dated May 28, 2004
10.35 ⁽⁶⁾⁺	Commercial Supply Agreement between the Registrant and Ceph International Corporation dated December 3, 2004
10.36 ⁽⁶⁾⁺	First Amendment to Development and Commercialization Agreement between the Registrant and Par Pharmaceutical Corporation dated December 14, 2004
10.37 ⁽⁷⁾⁺	Manufacturing and Supply Agreement between the Registrant and Clonmel Healthcare Limited, dated as of April 19, 2005.
10.38 ⁽⁷⁾⁺	Development and Clinical Manufacturing Agreement between the Registrant and Clonmel Healthcare Limited, dated as of April 19, 2005.
10.39 ⁽⁷⁾⁺	Facility Build-Out Agreement between the Registrant and Clonmel Healthcare Limited, dated as of April 19, 2005.
10.40 ⁽⁸⁾⁺	Form of Purchase Agreement dated April 26, 2005, including the form of Warrant attached thereto.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a) Certification of Principal Executive Officer
31.2	Rule 13a-14(a) Certification of Principal Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer

⁽¹⁾ Incorporated by reference to our Current Report on Form 8-K filed July 15, 2004.

⁽²⁾ Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-107599).

⁽³⁾ Incorporated by reference to our Quarterly Report on Form 10-Q filed August 6, 2004

⁽⁴⁾ Incorporated by reference to our definitive proxy statement filed April 22, 2005.

⁽⁵⁾ Incorporated by reference to our Registration Statement on Form S-8 (File No. 333-109728).

- (6) Incorporated by reference to our Annual Report on Form 10-K filed March 10, 2005
- (7) Incorporated by reference to our Quarterly Report on Form 10-Q filed August 15, 2005.
- (8) Incorporated by reference to our Current Report on Form 8-K dated April 27, 2005.
- † The Schedules and certain of the Exhibits to this Asset Purchase Agreement have been omitted in reliance upon the rules of the Securities and Exchange Commission. A copy will be delivered to the Securities and Exchange Commission upon request.
- + Confidential treatment has been granted for certain portions of this Exhibit pursuant to Rule 406 under the Securities Act, which portions are omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ADVANCIS PHARMACEUTICAL CORPORATION

By /s/ EDWARD M. RUDNIC
Edward M. Rudnic, Ph.D.
President and Chief Executive Officer

Dated: March 27, 2006

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ R. GORDON DOUGLAS</u> R. Gordon Douglas, M.D.	Chairman of the Board of Directors	March 27, 2006
<u>/s/ EDWARD M. RUDNIC</u> Edward M. Rudnic, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2006
<u>/s/ ROBERT C. LOW</u> Robert C. Low	Vice President — Finance, Acting Chief Financial Officer, Treasurer and Controller (Principal Financial and Accounting Officer)	March 27, 2006
<u>/s/ JAMES H. CAVANAUGH</u> James H. Cavanaugh, Ph.D.	Director	March 27, 2006
<u>/s/ RICHARD W. DUGAN</u> Richard W. Dugan	Director	March 27, 2006
<u>/s/ WAYNE T. HOCKMEYER</u> Wayne T. Hockmeyer, Ph.D.	Director	March 27, 2006
<u>/s/ HAROLD R. WERNER</u> Harold R. Werner	Director	March 27, 2006

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Shareholders of Advancis Pharmaceutical Corporation:

We have completed integrated audits of Advancis Pharmaceutical Corporation's 2005 and 2004 financial statements and of its internal control over financial reporting as of December 31, 2005 and an audit of its 2003 financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Financial statements and financial statement schedule

In our opinion, the financial statements listed in the accompanying index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Advancis Pharmaceutical Corporation at December 31, 2005 and December 31, 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Internal control over financial reporting

Also, in our opinion, management's assessment, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control — Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable

assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland
March 27, 2006

ADVANCIS PHARMACEUTICAL CORPORATION
BALANCE SHEETS

	December 31,	
	2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,116,968	\$ 10,395,757
Marketable securities	11,314,090	19,656,180
Restricted cash	418,244	—
Accounts receivable, net	756,764	350,116
Notes receivable from officer	121,500	—
Inventories, net	219,451	179,738
Prepaid expenses and other current assets	797,253	1,044,389
Total current assets	31,744,270	31,626,180
Property and equipment, net	14,450,627	16,524,342
Restricted cash	1,182,680	1,913,314
Deposits	884,312	264,125
Notes receivable from officer	—	121,500
Intangible assets, net	9,535,003	10,692,679
Total assets	<u>\$ 57,796,892</u>	<u>\$ 61,142,140</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,686,487	\$ 3,886,563
Accrued expenses and advances	7,071,731	4,305,115
Lines of credit — current portion	895,204	1,009,975
Deferred contract revenue	—	2,552,357
Total current liabilities	9,653,422	11,754,010
Lines of credit — noncurrent portion	597,208	1,492,412
Note payable	75,000	75,000
Accrued severance — noncurrent portion	1,235,394	—
Deferred contract revenue	11,625,000	6,861,111
Deferred rent and credit on lease concession	1,268,857	1,221,228
Total liabilities	24,454,881	21,403,761
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; no shares issued or outstanding at December 31, 2005 and 2004	—	—
Common stock, \$0.01 par value; 225,000,000 shares authorized, and 29,765,139 and 22,706,679 shares issued and outstanding at December 31, 2005 and 2004, respectively	297,652	227,067
Capital in excess of par value	144,766,213	120,315,949
Deferred stock-based compensation	(623,051)	(2,607,247)
Accumulated deficit	(111,095,308)	(78,106,731)
Accumulated other comprehensive loss	(3,495)	(90,659)
Total stockholders' equity	33,342,011	39,738,379
Total liabilities and stockholders' equity	<u>\$ 57,796,892</u>	<u>\$ 61,142,140</u>

The accompanying notes are an integral part of these financial statements.

ADVANCIS PHARMACEUTICAL CORPORATION

STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2005	2004	2003
Revenue:			
Product sales	\$ 4,809,222	\$ 2,396,500	\$ —
Contract revenue	4,027,778	5,347,223	3,625,000
Reimbursement of development costs	8,010,690	3,614,309	—
Total revenue	<u>16,847,690</u>	<u>11,358,032</u>	<u>3,625,000</u>
Costs and expenses:			
Cost of product sales	562,009	169,854	—
Research and development	39,729,441	33,642,930	16,594,629
Selling, general and administrative	10,515,302	12,219,409	6,427,453
Total expenses	<u>50,806,752</u>	<u>46,032,193</u>	<u>23,022,082</u>
Loss from operations	(33,959,062)	(34,674,161)	(19,397,082)
Interest income	1,075,084	793,818	253,504
Interest expense	(120,891)	(124,370)	(164,939)
Beneficial conversion feature — deemed interest expense	—	—	(1,666,667)
Other income	16,292	—	—
Net loss	(32,988,577)	(34,004,713)	(20,975,184)
Accretion of issuance costs of mandatorily redeemable convertible preferred stock	—	—	(209,173)
Beneficial conversion feature — deemed dividend to preferred stockholders	—	—	(20,907,620)
Net loss applicable to common stockholders	<u>\$(32,988,577)</u>	<u>\$(34,004,713)</u>	<u>\$(42,091,977)</u>
Basic and diluted net loss per share applicable to common stockholders	<u>\$ (1.20)</u>	<u>\$ (1.50)</u>	<u>\$ (7.58)</u>
Shares used in calculation of basic and diluted net loss per share	<u>27,421,516</u>	<u>22,684,410</u>	<u>5,554,773</u>

The accompanying notes are an integral part of these financial statements.

ADVANCIS PHARMACEUTICAL CORPORATION

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Common Shares	Par Value	Capital in Excess of Par Value	Deferred Stock-Based Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
Balance at December 31, 2002	1,376,306	\$ 13,763	\$ 514,598	\$ (102,986)	\$ (23,126,834)	\$ —	\$(22,701,459)
Issuance of restricted stock	173,532	1,735	89,359	—	—	—	91,094
Accretion of issuance costs of mandatorily redeemable convertible preferred stock	—	—	(209,173)	—	—	—	(209,173)
Cashless exercise of warrants	27,032	271	(301)	—	—	—	(30)
Issuance and remeasurement of stock options for services	—	—	1,260,117	—	—	—	1,260,117
Deferred stock-based compensation	—	—	8,204,446	(8,204,446)	—	—	—
Amortization of deferred stock-based compensation	—	—	—	2,181,146	—	—	2,181,146
Beneficial conversion feature — deemed interest on convertible notes	—	—	1,666,667	—	—	—	1,666,667
Beneficial conversion feature — deemed dividend on issuance of Series E preferred stock	—	—	20,907,620	—	—	—	20,907,620
Accretion of beneficial conversion feature — deemed dividend	—	—	(20,907,620)	—	—	—	(20,907,620)
Issuance of common stock in public offering, net of issuance costs	6,000,000	60,000	54,251,900	—	—	—	54,311,900
Conversion of preferred stock to common stock	15,062,474	150,625	54,363,837	—	—	—	54,514,462
Comprehensive income (loss):							
Net loss	—	—	—	—	(20,975,184)	—	(20,975,184)
Unrealized gain on marketable securities, net	—	—	—	—	—	10,380	10,380
Total comprehensive loss	—	—	—	—	—	—	(20,964,804)
Balance at December 31, 2003	22,639,344	226,394	120,141,450	(6,126,286)	(44,102,018)	10,380	70,149,920
Exercise of stock options	26,764	268	15,976	—	—	—	16,244
Issuance of restricted stock	40,571	405	24,305	—	—	—	24,710
Issuance and remeasurement of stock options for services	—	—	26,370	—	—	—	26,370
Stock-based compensation for retired director	—	—	416,141	73,810	—	—	489,951
Amortization of deferred stock-based compensation	—	—	—	3,296,898	—	—	3,296,898
Reversal of deferred stock-based compensation and related amortization due to forfeited options	—	—	(308,293)	148,331	—	—	(159,962)
Comprehensive income (loss):							
Net loss	—	—	—	—	(34,004,713)	—	(34,004,713)
Unrealized loss on marketable securities, net	—	—	—	—	—	(101,039)	(101,039)
Total comprehensive loss	—	—	—	—	—	—	(34,105,752)
Balance at December 31, 2004	22,706,679	227,067	120,315,949	(2,607,247)	(78,106,731)	(90,659)	39,738,379
Exercise of stock options	171,155	1,712	98,783	—	—	—	100,495
Issuance of restricted stock	40,570	406	24,305	—	—	—	24,711
Issuance and remeasurement of stock options for services	—	—	(123,149)	—	—	—	(123,149)
Amortization of deferred stock-based compensation	—	—	—	1,522,554	—	—	1,522,554
Reversal of deferred stock-based compensation and related amortization due to forfeited options	—	—	(1,325,261)	461,642	—	—	(863,619)
Proceeds from private placement of common stock and warrants, net of issuance expenses	6,846,735	68,467	25,775,586	—	—	—	25,844,053
Comprehensive income (loss):							
Net loss	—	—	—	—	(32,988,577)	—	(32,988,577)
Unrealized gain on marketable securities, net	—	—	—	—	—	87,164	87,164
Total comprehensive loss	—	—	—	—	—	—	(32,901,413)
Balance at December 31, 2005	<u>29,765,139</u>	<u>\$297,652</u>	<u>\$144,766,213</u>	<u>\$ (623,051)</u>	<u>\$(111,095,308)</u>	<u>\$ (3,495)</u>	<u>\$ 33,342,011</u>

The accompanying notes are an integral part of these financial statements.

ADVANCIS PHARMACEUTICAL CORPORATION
STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2005	2004	2003
Cash flows from operating activities:			
Net loss	\$(32,988,577)	\$(34,004,713)	\$(20,975,184)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,044,419	2,714,341	736,036
Stock-based compensation	535,786	3,653,257	3,441,263
Deferred rent and credit on lease concession	47,629	453,469	(62,251)
Amortization of premium on marketable securities	253,483	1,297,947	231,600
Interest accrued on convertible notes	—	—	92,362
Beneficial conversion feature — deemed interest expense	—	—	1,666,667
Gain on disposal of fixed assets	(16,292)	—	—
Changes in:			
Accounts receivable	(406,648)	2,649,884	(3,000,000)
Inventories	(39,713)	(179,738)	—
Prepaid expenses and other current assets	247,136	83,075	(954,952)
Deposits other than on property and equipment	(62,394)	(49,142)	95,068
Accounts payable	(2,200,076)	1,202,850	1,924,940
Accrued expenses and accrued severance	3,483,910	1,653,637	1,345,211
Deferred contract revenue	2,211,532	5,038,468	4,375,000
Net cash used in operating activities	(24,889,805)	(15,486,665)	(11,084,240)
Cash flows from investing activities:			
Purchase of Keflex intangible assets	—	(11,205,517)	—
Advance payment for potential sale of Keflex intangible assets	1,000,000	—	—
Purchase of marketable securities	(15,029,229)	(25,918,898)	(27,857,852)
Sale and maturities of marketable securities	23,205,000	32,500,364	—
Purchases of property and equipment	(1,365,088)	(6,200,677)	(8,963,111)
Deposits on property and equipment	(557,793)	(759,638)	(83,610)
Proceeds from sale of fixed assets	111,163	—	—
Restricted cash	312,390	(136,745)	(338,031)
Landlord lease concession	—	—	830,010
Net cash from (used in) investing activities	7,676,443	(11,721,111)	(36,412,594)
Cash flows from financing activities:			
Proceeds from lines of credit	—	1,389,396	1,346,061
Payments on lines of credit	(1,009,975)	(1,252,597)	(636,407)
Proceeds from convertible notes payable	—	—	5,000,000
Proceeds from exercise of common stock options	100,495	16,244	91,094
Proceeds from private placement of common stock and warrants, net of issuance costs	25,844,053	—	—
Proceeds from issuance of preferred stock, net of issuance costs	—	—	20,774,765
Proceeds from initial public offering, net of issuance costs	—	—	54,311,900
Net cash from financing activities	24,934,573	153,043	80,887,413
Net increase (decrease) in cash and cash equivalents	7,721,211	(27,054,733)	33,390,579
Cash and cash equivalents, beginning of period	10,395,757	37,450,490	4,059,911
Cash and cash equivalents, end of period	\$ 18,116,968	\$ 10,395,757	\$ 37,450,490
Supplemental disclosure of cash flow information:			
Cash paid for interest, net of interest capitalized	\$ 120,891	\$ 127,094	\$ 38,511
Supplemental disclosure of non-cash transactions:			
Reclassification of liability related to early exercises of restricted stock to equity upon vesting of the restricted stock	\$ 24,711	\$ 24,710	\$ 3,537
Equipment and construction costs in accrued liabilities	\$ —	\$ 457,189	\$ 1,580,509
Conversion of convertible notes, including accrued interest, into Series E mandatorily redeemable convertible preferred stock	\$ —	\$ —	\$ 5,092,362
Accretion of beneficial conversion feature for Series E convertible preferred stock	\$ —	\$ —	\$ 20,907,620
Conversion of preferred stock to common	\$ —	\$ —	\$ 54,514,462
Accretion of issuance costs of mandatorily redeemable convertible preferred stock	\$ —	\$ —	\$ 209,173

The accompanying notes are an integral part of these financial statements.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS

1. Nature of the Business

Advancis Pharmaceutical Corporation (the "Company") was incorporated in Delaware in December 1999 and commenced operations on January 1, 2000. The Company is focused on developing and commercializing anti-infective drug products that fulfill unmet medical needs in the treatment of infectious disease. The Company is developing a portfolio of drugs based on the novel biological finding that bacteria exposed to antibiotics in front-loaded, sequential bursts, or pulses, are killed more efficiently than those exposed to standard antibiotic treatment regimens. The Company has initially focused on developing pulsatile formulations of approved and marketed drugs that no longer have patent protection or that have patents expiring in the next several years. In 2004, the Company acquired the U.S. rights to Keflex (cephalexin capsules, USP) from Eli Lilly and commenced product sales.

The Company is devoting substantially all of its efforts to conducting clinical trials, pursuing regulatory approval for products under development, engaging in preclinical development, and promoting sales of Keflex products. The Company began in 2004 to generate product revenues but has not achieved profitable operations or positive cash flows from operations. There is no assurance that profitable operations can be achieved or sustained on a continuing basis. The Company's future operations are dependent on the success of the Company in commercializing new Keflex products, completing clinical trials, and commercializing its pulsatile drug product candidates.

2. Summary of Significant Accounting Policies

Use of Estimates and Reclassifications

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Certain reclassifications of prior period amounts have been made to the financial statements to conform to the current period presentation.

Revenue Recognition

Product sales revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectibility is reasonably assured. Revenues are reduced at the time of sale to reflect expected returns, discounts, rebates, and chargebacks. These estimates are based on terms, historical experience, trend analysis, and market conditions.

Contract revenues include license fees and milestone payments associated with collaborations with third parties. Revenue from non-refundable, upfront license fees where the Company has continuing involvement is recognized ratably over the development or agreement period. Revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements.

Revenue for reimbursement of development costs is recognized as the actual costs to perform the work are incurred. Revenue recognized is limited to minimum amounts expected to be received under the specific agreements and excludes amounts contingent on future events, such as successful commercialization, and amounts that are contingently refundable.

Deferred contract revenue represents cash received in excess of revenue recognized.

Research and Development

The Company expenses research and development costs as incurred. Research and development costs primarily consist of salaries and related expenses for personnel, fees paid to consultants and outside service

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

providers, including clinical research organizations for the conduct of clinical trials, costs of materials used in clinical trials and research and development, development costs for contract manufacturing prior to FDA approval of products, depreciation of capital resources used to develop products, and costs of facilities.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, commercial paper and high-quality corporate bonds. At December 31, 2005 and 2004, the Company maintained all of its cash and cash equivalents in three financial institutions. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand, and the Company believes there is minimal risk of losses on such cash balances.

Restricted Cash

The Company has established cash deposit accounts in the amounts of \$41,924 and \$500,000 as of December 31, 2005, and \$337,604 and \$516,710 as of December 31, 2004, that are pledged as collateral for lines of credit (see Note 9). Also, in conjunction with the lease of its corporate, research and development facilities, the Company provided the landlord with letters of credit, which were collateralized with restricted cash deposits in the amount of \$1,059,000 at December 31, 2005 and December 31, 2004 (see Note 19). These deposits are recorded as non-current restricted cash at December 31, 2005 and 2004.

Marketable Securities

The Company classifies all of its marketable securities as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported as a component of stockholders' equity (deficit) in accumulated other comprehensive income (loss). Marketable securities available for current operations are classified in the balance sheet as current assets. Interest income, net of amortization of premium on marketable securities, and realized gains and losses on securities are included in "Interest income" in the statements of operations.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, marketable securities, notes payable and line of credit borrowings, approximate their fair values due to their short maturities.

Accounts Receivable, net

Accounts receivable represent amounts due from wholesalers for sales of pharmaceutical products. Allowances for estimated product returns, discounts, and chargebacks are recorded as reductions to accounts receivable. Amounts due for estimated rebates payable to third parties are included in accrued liabilities.

Inventories, net

Inventories consist of finished products purchased from third parties and are stated at the lower of cost or market. Cost is determined on the first-in, first-out (FIFO) method. Reserves for obsolete or slow-moving inventory are recorded as reductions to inventory cost.

Property and Equipment

Property and equipment are stated at cost and depreciated over their estimated useful lives using the straight-line method. Leasehold improvements are capitalized and amortized over the shorter of their economic life or the

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

lease term. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred. In accordance with SFAS No. 34, "*Capitalization of Interest Cost*," the Company capitalized interest cost of \$103,446 in the year ended December 31, 2003 related to the build-out of its corporate, research and development facility. No interest was capitalized in the years ended December 31, 2005 and 2004.

Intangible Assets

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives. The Keflex brand rights are amortized over 10 years, the Keflex non-compete agreement with Eli Lilly and Company is amortized over 5 years, and certain acquired patents are amortized over 10 years. The Company does not have identifiable intangible assets with indefinite lives. The Keflex brand name and other intangible assets were acquired for marketing purposes, and the related amortization is charged to selling expense.

Patents are carried at cost less accumulated amortization which is calculated on a straight-line basis over the estimated useful lives of the patents. The Company periodically reviews the carrying value of patents to determine whether the carrying amount of the patent is recoverable. For the years ended December 31, 2005, 2004 and 2003, there were no adjustments to the carrying values of patents. The Company is amortizing the cost of the patent applications over a period of 10 years. Ownership of all of its patents is retained by the Company in all of its transactions.

Impairment of Long-Lived Assets

SFAS No. 144, "*Accounting for the Impairment or Disposal of Long-Lived Assets*," establishes accounting standards for the impairment of long-lived assets. The Company reviews its long-lived assets, including property and equipment and intangible assets, for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. If this review indicates that the asset will not be recoverable based on the expected undiscounted net cash flows of the related asset, an impairment loss is recognized. There were no impairment losses recognized in 2005, 2004 or 2003.

Leases

The Company leases its office and laboratory facilities under operating leases. Lease agreements may contain provisions for rent holidays, rent escalation clauses or scheduled rent increases, and landlord lease concessions such as tenant improvement allowances. The effects of rent holidays and scheduled rent increases in an operating lease are recognized over the term of the lease, including the rent holiday period, so that rent expense is recognized on a straight-line basis. For lease concessions such as tenant improvement allowances, the Company records a deferred rent liability included in "Deferred rent and credit on lease concession" on the balance sheet and amortizes the deferred liability on a straight-line basis as a reduction to rent expense over the term of the lease. The tenant improvements are capitalized as a leasehold improvement and is amortized over the shorter of the economic life of the improvement or the lease term (excluding optional renewal periods). Amortization of leasehold improvements is included in depreciation expense. The Company's leases do not include contingent rent provisions.

Accounting for Stock-Based Compensation

Employee stock awards under the Company's compensation plans are accounted for by the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*," (APB 25) and related interpretations. During 2003 and 2002, stock options were granted with an exercise price which was below the estimated fair market value of the common stock at the date of grant. Accordingly, deferred stock-based compensation of \$8,204,446 and \$132,940 was recorded during 2003 and 2002, respectively, in accordance with APB 25, and amortization of deferred stock-based compensation is charged to

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

operations over the related vesting periods of the options. No deferred stock-based compensation was recorded in 2005 or 2004, as all options granted to employees during those years had an exercise price equal to the market value of the underlying common stock on the date of grant.

In accordance with SFAS 148, the following table illustrates the effect on net loss and net loss per share as if the Company had applied the fair value recognition provisions of SFAS 123. Because options vest over several years and additional option grants are expected to be made in future years, the pro forma results are not representative of the pro forma results for future years.

	December 31,		
	2005	2004	2003
Net loss, as reported	\$(32,988,577)	\$(34,004,713)	\$(20,975,184)
Add — Stock-based employee compensation expense determined under the intrinsic value method	658,935	3,626,887	2,181,146
Less — Stock-based employee compensation expense determined under the fair value based method	<u>(3,298,472)</u>	<u>(8,491,814)</u>	<u>(2,677,989)</u>
Pro forma net loss	<u>(35,628,114)</u>	<u>(38,869,640)</u>	<u>(21,472,027)</u>
Accretion of issuance costs of mandatorily redeemable convertible preferred stock	—	—	(209,173)
Beneficial conversion feature-deemed dividend to preferred stockholders	<u>—</u>	<u>—</u>	<u>(20,907,620)</u>
Pro forma net loss applicable to common stockholders	<u>\$(35,628,114)</u>	<u>\$(38,869,640)</u>	<u>\$(42,588,820)</u>
Net loss per share:			
Basic and diluted, as reported	<u>\$ (1.20)</u>	<u>\$ (1.50)</u>	<u>\$ (7.58)</u>
Basic and diluted, pro forma	<u>\$ (1.30)</u>	<u>\$ (1.71)</u>	<u>\$ (7.67)</u>

The weighted average fair value of options granted during 2005, 2004 and 2003 was \$2.13, \$5.33, and \$8.03 per share, respectively. The fair value of each option grant was estimated on the date of grant using the Black-Scholes options pricing model with the following assumptions for grants in 2005, 2004 and 2003:

	December 31,		
	2005	2004	2003
Expected life (in years)	5	5	5
Risk-free interest rate	3.81%	4.09%	3.28%
Volatility	79.6%	80.0%	80.0%
Dividend yield	0%	0%	0%

The Company's common stock has been publicly — traded since its initial public offering in October 2003. Due to the limited trading history, the Company establishes its estimate for volatility by considering the volatility of the stock of other comparable public companies.

Income Taxes

The Company accounts for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Comprehensive Income

SFAS No. 130, "Reporting Comprehensive Income," requires a full set of general-purpose financial statements to include the reporting of "comprehensive income." Comprehensive income is composed of two components, net income and other comprehensive income. For the years ended December 31, 2005, 2004 and 2003, other comprehensive income (loss) of \$87,164, \$(101,039) and \$10,380, respectively, consists of unrealized gains and losses on available-for-sale marketable securities.

Earnings Per Share

Basic earnings per share is computed based on the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed based on the weighted average shares outstanding adjusted for all dilutive potential common shares. The dilutive impact, if any, of potential common stock outstanding during the period, including outstanding stock options and warrants, is measured by the treasury stock method. The dilutive impact, if any, of the Company's redeemable convertible preferred stock is measured using the if-converted method. Potential common shares are not included in the computation of diluted earnings per share if they are antidilutive. The Company incurred net losses for 2005, 2004 and 2003 and, accordingly, did not assume exercise or conversion of any of the Company's outstanding stock options, warrants or redeemable convertible preferred stock because to do so would be antidilutive.

The following are the securities that could potentially dilute basic earnings per share in the future that were not included in the computation of diluted earnings per share because to do so would have been antidilutive for the periods presented:

(Number of Underlying Common Shares)	December 31,		
	2005	2004	2003
Stock options	4,095,417	3,736,726	2,235,488
Nonvested restricted stock	71,032	237,689	424,290
Warrants	<u>2,396,357</u>	<u>—</u>	<u>—</u>
Total	<u>6,562,806</u>	<u>3,974,415</u>	<u>2,659,778</u>

Segment and Geographic Information

In accordance with SFAS No. 131, "Disclosure about Segments of an Enterprise and Related Information," the Company has determined that it operates in one business segment. The Company is organized along functional lines of responsibility and does not utilize a product, divisional or regional organizational structure. The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

The Company sells its products to a limited number of pharmaceutical wholesalers, and all product sales occur in the United States. Long-lived assets, consisting of property and equipment, are located both in the United States and Ireland.

<u>Geographic Information</u>	<u>Product Sales</u>	<u>Long-Lived Assets</u>
United States	\$4,809,222	\$13,065,518
Ireland	—	1,385,109
Total	<u>\$4,809,222</u>	<u>\$14,450,627</u>

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS 123R, “*Share-Based Payment*,” a revision of SFAS 123, “*Accounting for Stock-based Compensation*.” SFAS 123R requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use APB 25’s intrinsic value method of accounting for share-based payments. Accordingly, the Company plans to begin recognizing the expense associated with its share-based payments, as determined using a fair value-based method, in its statement of operations beginning on January 1, 2006. Adoption of the expense provisions of SFAS 123R is expected to have a material, noncash impact on the Company’s results of operations. The standard allows alternative transition methods for public companies. The Company expects to adopt the modified prospective application method as its transition method. Under this method, prior periods will not be restated. Compensation cost for the unvested portion of awards that are outstanding as of January 1, 2006 will be recognized as the requisite service is rendered on or after the effective date. The compensation cost for the unvested portion of those earlier awards will be based on the fair value at date of grant as calculated in the Company’s pro forma disclosure under SFAS 123, net of estimated forfeitures.

In February 2005, the EITF added to its agenda Issue No. 05-4, “*The Effect of a Liquidated Damages Clause on a Freestanding Financial Instrument Subject to EITF Issue No. 00-19, ‘Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock.’*” The issue addresses liquidated damages provisions associated with registration rights agreements and the diversity in practice that exists in accounting for such provisions. In June 2005 and September 2005, the EITF discussed the Issue but did not reach a consensus. Further deliberations by the EITF have been postponed until the FASB addresses whether a registration rights agreement is a derivative. The Company is monitoring the progress of the FASB and EITF on this Issue.

In May 2005, the FASB issued SFAS 154, “*Accounting Changes and Error Corrections — a Replacement of APB Opinion No. 20 and FASB Statement No. 3.*” SFAS 154 generally requires retrospective application to prior periods’ financial statements of voluntary changes in accounting principles. Under the prior rules, changes in accounting principles were generally recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. This statement does not change the previous requirements for reporting the correction of an error in previously issued financial statements, change in accounting estimate, or justification of a change in accounting principle on the basis of preferability. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 31, 2005. Adoption of the provisions of this statement is not expected to have a material effect on the results of operations or financial position of the Company.

In November 2005, the FASB Staff issued FASB Staff Position (“FSP”) FAS 115-1, “*The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.*” FSP FAS 115-1 addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. It also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP is effective for reporting

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

periods beginning after December 15, 2005. FSP FAS 115-1 is not expected to have a material effect on the Company's financial statements.

3. Revenue

The Company records revenue from the sale of pharmaceutical products (Keflex) and from the recognition of revenue earned under collaboration agreements.

Product Sales. The Company's largest customers are large wholesalers of pharmaceutical products. Cardinal Health, McKesson, and AmerisourceBergen accounted for approximately 59.7%, 20.9%, and 13.7% of the Company's net revenues from product sales in the year ended December 31, 2005, and 51.1%, 27.7%, and 16.6% of the Company's net revenues from product sales in the year ended December 31, 2004, respectively.

Contract Revenue. Revenue recognized for upfront payments and milestones under collaboration agreements is as follows:

<u>Contract Revenue</u>	<u>December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Upfront payment — GSK — amortization	\$ —	\$1,145,833	\$ 625,000
Upfront payment — GSK — acceleration upon termination	—	3,229,167	—
Milestone achievement — GSK	—	—	3,000,000
Upfront payment — Par — amortization	796,783	972,223	—
Upfront payment — Par — acceleration upon termination	<u>3,230,995</u>	<u>—</u>	<u>—</u>
Total	<u>\$4,027,778</u>	<u>\$5,347,223</u>	<u>\$3,625,000</u>

The GSK and Par collaborations have been terminated, and the Company currently has no other collaborations in place that would provide future funding or revenue.

Reimbursement of Development Costs. Revenue recognized for reimbursement by third parties of research and development costs is as follows:

<u>Reimbursement of Development Costs</u>	<u>December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Reimbursement by Par of period costs incurred	\$5,635,690	\$3,614,309	\$—
Acceleration upon termination of Par collaboration	<u>2,375,000</u>	<u>—</u>	<u>—</u>
Total	<u>\$8,010,690</u>	<u>\$3,614,309</u>	<u>\$—</u>

Collaboration with GlaxoSmithKline (GSK). In July 2003, the Company entered into a development and license agreement with GSK pursuant to which the Company exclusively licensed patents and PULSYS technology to GSK for potential use on some of its products. In consideration for the licensing of its technology, the Company received an upfront payment of \$5.0 million, which was being amortized over the expected development period. The Company recognized revenue of \$1,145,833 and \$625,000 in the years ended December 31, 2004 and 2003, respectively, for the amortization of the \$5,000,000 upfront payment based on the original development schedule of GSK. Also, in December 2003, the Company was notified by GSK that the first milestone event was achieved, and the Company recognized revenue of \$3,000,000 for this event in 2003. In 2004, GSK notified the Company that it would terminate this agreement, effective December 15, 2004. As a result, the remaining deferred revenue balance of \$3,229,167 was recognized as revenue in the fourth quarter of 2004.

Collaboration with Par Pharmaceutical for Amoxicillin PULSYS. In May 2004, the Company entered into an agreement with Par Pharmaceutical to collaborate in the further development and commercialization of a PULSYS-

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

based amoxicillin product. Under the terms of the agreement, the Company conducted the development program, including the manufacture of clinical supplies and the conduct of clinical trials, and was responsible for obtaining regulatory approval for the product. The Company was to own the product trademark and was to manufacture or arrange for supplies of the product for commercial sales. Par was to be the sole distributor of the product. Both parties were to share commercialization expenses, including pre-marketing costs and promotion costs, on an equal basis. Operating profits from sales of the product were also to be shared on an equal basis. Under the agreement, the Company received an upfront fee of \$5,000,000 and a commitment from Par to fund all further development expenses. Development expenses incurred by the Company were to be partially funded by quarterly payments aggregating \$28 million over the period of July 2004 through October 2005, of which up to \$14 million is contingently refundable.

Revenue related to the receipt of the quarterly payments from Par was recognized based on actual costs incurred as the work was performed, limited to the minimum amounts expected to be received under the agreement and excluding amounts contingent on future events or that were contingently refundable, with the balance of cash received in excess of revenue recognized recorded as deferred revenue. The excess of the development costs incurred by the Company over the quarterly payments made by Par was to be funded subsequent to commercialization, by the distribution to the Company of Par's share of operating profits until the excess amount had been reimbursed. The Company did not record any amounts as revenue on a current basis that were dependent on achievement of future operating profits.

On August 3, 2005, the Company was notified by Par that Par decided to terminate the companies' Amoxicillin PULSYS collaboration agreement. Advancis received from Par the \$4,750,000 development funding quarterly payment due in July 2005 and expects no further payments under the collaboration. Under certain circumstances, the termination clauses of the agreement may entitle Par to receive a share of net profits up to one-half of their cumulative \$23,250,000 funding of the development costs of certain Amoxicillin PULSYS products, should a product covered by the agreement be successfully commercialized. Accordingly, in 2005 the Company retained deferred revenue of \$11,625,000 related to the agreement, and accelerated the recognition into current revenue of the remaining balance of \$2,375,000 of deferred reimbursement revenue.

Revenue related to the \$5,000,000 upfront fee was being amortized into contract revenue on a straight-line basis over the estimated development period. As a result of the termination, the Company recognized the remaining deferred revenue balance of \$3,230,995 related to the upfront fee as revenue in 2005.

4. Marketable Securities

Marketable securities, including accrued interest, at December 31, 2005 and 2004 were as follows:

<u>Available-for-sale</u>	<u>December 31, 2005</u>			
	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Marketable securities:				
Corporate debt securities:				
-In unrealized gain position	\$ 1,988,491	\$2,173	\$ —	\$ 1,990,664
-In unrealized loss position under 12 months	7,820,334	—	(3,095)	7,817,239
-In unrealized loss position over 12 months	1,508,760	—	(2,573)	1,506,187
	<u>\$11,317,585</u>	<u>\$2,173</u>	<u>\$(5,668)</u>	<u>\$11,314,090</u>

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

<u>Available-for-sale</u>	<u>December 31, 2004</u>			<u>Fair Value</u>
	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	
Marketable securities:				
Corporate debt securities	\$16,736,347	\$—	\$(72,670)	\$16,663,677
Government agency securities	<u>3,010,492</u>	<u>—</u>	<u>(17,989)</u>	<u>2,992,503</u>
	<u>\$19,746,839</u>	<u>\$—</u>	<u>\$(90,659)</u>	<u>\$19,656,180</u>

At December 31, 2005, there was one security in an unrealized loss position for greater than 12 months, and seven securities in an unrealized loss position for less than 12 months. The unrealized losses on the Company's investments in corporate debt securities were caused by interest rate increases. The contractual terms of these investments do not permit the issuer to settle the securities at a price less than the amortized cost of the investment. Because the decline in market value is attributable to changes in interest rates and not credit quality, and because the Company has the ability and intent to hold these investments until a recovery of fair value, which may be maturity, the Company does not consider these investments to be other-than-temporarily impaired at December 31, 2005. In 2005, the Company did not experience any realized losses in its marketable securities portfolio.

Each of the Company's marketable securities at December 31, 2005 matures within six months.

5. Accounts Receivable

Accounts receivable, net, consists of the following:

	<u>December 31, 2005</u>	<u>December 31, 2004</u>
Accounts receivable for product sales, gross	\$1,109,685	\$ 478,684
Allowances for discounts, wholesaler rebates, and chargebacks	<u>(352,920)</u>	<u>(128,568)</u>
Accounts receivable for product sales, net	<u>\$ 756,765</u>	<u>\$ 350,116</u>

The Company's largest customers are large wholesalers of pharmaceutical products. Accounts receivable, gross, at December 31, 2005 includes \$988,332 due from wholesalers and \$121,353 due from Eli Lilly for reimbursement of wholesaler returns activity due under the Keflex transition agreement. Of the amount due from wholesalers, three of these large wholesalers accounted for approximately 80.7%, 10.4% and 6.4% of the Company's accounts receivable for product sales as of December 31, 2005, and 53.4%, 24.3%, and 16.6% as of December 31, 2004.

6. Inventories

Inventories, net, consist of the following:

	<u>December 31, 2005</u>	<u>December 31, 2004</u>
Finished goods	\$ 373,818	\$179,738
Reserve for obsolete and slow-moving inventory	<u>(154,367)</u>	<u>—</u>
Inventories, net	<u>\$ 219,451</u>	<u>\$179,738</u>

The Company periodically reviews its product inventories on hand. Inventory levels are evaluated by management relative to product demand, remaining shelf life, future marketing plans and other factors, and reserves for obsolete and slow-moving inventories are recorded for amounts which may not be realizable.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

7. Property and Equipment

Property and equipment consist of the following:

	Estimated Useful Life (Years)	December 31,	
		2005	2004
Construction in progress	n/a	\$ 535,463	\$ 459,148
Computer equipment	3	1,010,757	1,003,229
Furniture and fixtures	3-10	1,405,918	1,355,643
Equipment	3-10	9,197,693	8,589,960
	Shorter of economic life or		
Leasehold improvements	lease term	8,719,668	8,715,920
Subtotal		20,869,499	20,123,900
Less — accumulated depreciation		(6,418,872)	(3,599,558)
Total		<u>\$14,450,627</u>	<u>\$16,524,342</u>

Depreciation expense for the years ended December 31, 2005, 2004 and 2003 was \$2,886,743, \$2,129,501, and \$724,036, respectively.

8. Intangible Assets

Intangible assets at December 31, 2005 and December 31, 2004 consist of the following:

	December 31, 2005		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Keflex brand rights	\$10,954,272	\$(1,643,148)	\$9,311,124
Keflex non-compete agreement	251,245	(75,366)	175,879
Patents acquired	120,000	(72,000)	48,000
Intangible assets	<u>\$11,325,517</u>	<u>\$(1,790,514)</u>	<u>\$9,535,003</u>

	December 31, 2004		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Keflex brand rights	\$10,954,272	\$(547,716)	\$10,406,556
Keflex non-compete agreement	251,245	(25,122)	226,123
Patents acquired	120,000	(60,000)	60,000
Intangible assets	<u>\$11,325,517</u>	<u>\$(632,838)</u>	<u>\$10,692,679</u>

On June 30, 2004, the Company acquired the U.S. rights to the Keflex brand of cephalexin from Eli Lilly and Company. The purchase price was \$11.2 million, including transaction costs, which was paid in cash from the Company's working capital. The identified intangible assets acquired consisted of the Keflex brand and a non-compete agreement with Lilly. The Company did not acquire customer lists or sales personnel from Lilly.

In the event the Company is able to develop and commercialize a PULSYS-based Keflex product, another cephalexin product relying on the acquired NDAs, or other pharmaceutical products using the acquired trademarks, Eli Lilly will be entitled to royalties on these new products. Royalties, at 10 percent of sales value, are payable on a

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

new product by new product basis for five years following the first commercial sale for each new product, up to a maximum aggregate royalty per calendar year. All royalty obligations with respect to any defined new product cease after the fifteenth anniversary of the first commercial sale of the first defined new product.

The fair market values of the individual Keflex intangible assets acquired were evaluated by an unrelated third party valuation consulting firm, and the Company has recorded the individual fair market values of these intangible assets accordingly. The allocation of the purchase price was:

Keflex brand rights	\$10,954,272
Keflex non-compete agreement	<u>251,245</u>
Total	<u>\$11,205,517</u>

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives. The Keflex brand rights are amortized over 10 years, the non-compete agreement with Lilly is amortized over 5 years, and certain acquired patents are amortized over 10 years.

Amortization expense for acquired intangible assets with definite lives was \$1,157,676, \$584,838, and \$12,000 for the years ending December 31, 2005, 2004 and 2003, respectively. For the next five years, annual amortization expense for acquired intangible assets is expected to be approximately \$1,200,000 for 2006, 2007 and 2008, and approximately \$1,100,000 for 2009 and 2010.

9. Borrowings

The Company's obligations on borrowings are as follows:

	December 31,	
	2005	2004
Lines of credit	\$1,492,412	\$2,502,387
Montgomery County note payable	<u>75,000</u>	<u>75,000</u>
Total	<u>\$1,567,412</u>	<u>\$2,577,387</u>

Principal payments under borrowings are as follows:

<u>Year Ending December 31,</u>	
2006	\$ 895,204
2007	621,755
2008	<u>50,453</u>
Total borrowings	1,567,412
Less: Current portion	<u>(895,204)</u>
Noncurrent portion	<u>\$ 672,208</u>

Lines of Credit

In January 2001, the Company entered into a \$1.5 million line of credit facility to finance the purchase of specified equipment based on lender-approved equipment schedules. The implicit interest rate is 11.62%. The Company has granted a security interest in the assets purchased under the credit line. During 2004 and 2003, the Company had no draw downs under the line of credit. During 2005 and 2004, the Company repaid \$10,573 and \$402,682, respectively. The balance outstanding at December 31, 2005 and 2004 was zero and \$10,573, respectively.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

In February 2002, the Company entered into a \$2.0 million line of credit facility to finance the purchase of specified equipment based on approved equipment schedules. The implicit interest rates were between 8.35% and 9.35%. The Company has granted a security interest in the assets purchased under the credit line. During 2005 and 2004, the Company had no draw downs under the line of credit. During 2005 and 2004, the Company repaid \$138,435 and \$152,598, respectively. The balance outstanding at December 31, 2005 and 2004 was \$115,389 and \$253,824, respectively.

In March 2002, the Company entered into a \$500,000 line of credit facility with a bank to finance the purchase of equipment. The interest rate is floating 30-Day LIBOR plus 250 basis points or fixed cost of funds plus 250 basis points. Each drawing requires monthly repayment of principal plus interest based upon a 48-month repayment schedule. The line of credit has a first lien on all assets purchased with the proceeds of this line. As of December 31, 2005, the Company has a \$41,924 restricted account (see Note 2) with the bank to be used as collateral for this line of credit. During 2005 and 2004, the Company had no draw downs under the line of credit and repaid \$123,076 each year. The balance outstanding at December 31, 2005 and 2004 was \$41,924 and \$165,000, respectively.

In July 2003, the Company entered into a \$5.5 million line of credit facility with a bank to finance the purchase of equipment associated with the fit-out of the Company's corporate, research and development facility. The facility has an interest rate of floating 30-Day LIBOR plus 280 basis points or fixed cost of funds plus 280 basis points. Each drawing requires monthly repayment of principal plus interest based upon a 36-month repayment schedule for computer equipment or a 48-month repayment schedule for all other equipment. The line of credit has a first lien on all assets purchased with the proceeds of the line. As collateral for the line of credit, the Company maintains a restricted account with the bank in the amount of \$500,000 (see Note 2). During 2005, the Company had no draws and repaid \$737,891. During 2004, the Company drew down \$1,389,396 and repaid \$574,241. The balance outstanding under this facility at December 31, 2005 and 2004 was approximately \$1,335,099 and \$2,072,990, respectively.

Montgomery County Note Payable

In December 2001, the Company entered into an Economic Development Fund Agreement with Montgomery County, Maryland. The primary purpose of the Economic Development Fund is to assist private employers who are located, planning to locate or substantially expand operations in Montgomery County. In September 2002, the Company received a \$75,000 loan from the County. The loan will be amortized over 5 years from the loan disbursement date, with a moratorium on both the principal and the interest payment, until the third anniversary of the loan. The interest rate is fixed at 5% per annum. The principal and accrued interest must be repaid by the fifth anniversary of the loan disbursement date in quarterly installments with the first quarterly payment due on the 15th day of the month following the moratorium expiration date. According to the agreement, the County will permanently forgive part or all of the \$75,000 loan principal balance together with the accrued interest if certain conditions relating to employment levels and capital investment are met. A final determination as to whether these conditions have been satisfied has not yet been made.

The Company must repay the entire \$75,000 if it relocates to a site outside Montgomery County, or moves all or substantial parts of its business outside the county, within 5 years of the date of the promissory note.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

10. Accrued Expenses and Advances

Accrued expenses and advances consist of the following:

	December 31,	
	2005	2004
Bonus	\$ 849,078	\$ 895,000
Professional fees	352,445	381,501
Relocation	—	120,305
Severance — current portion	1,870,479	286,515
Insurance and benefits	179,109	178,624
Liability for exercised unvested stock options	42,770	67,481
Research and development expenses	1,546,469	1,543,164
Product returns	791,282	144,115
Other expenses	440,099	231,221
Advance payment for potential sale of Keflex assets	1,000,000	—
Equipment and construction costs	—	457,189
Total accrued expenses and advances	<u>\$7,071,731</u>	<u>\$4,305,115</u>

Accrued Severance

In July and September 2005, the Company reduced its workforce a total of approximately 38% as part of a cost-saving initiative. It recorded a charge of \$3,973,265 for severance costs related to salaries and benefits, a non-cash benefit of \$512,488 for the reversal of cumulative amortization of deferred stock-based compensation related to forfeited stock options, and a charge of \$140,366 for the remaining cost of the New Jersey office lease. In November 2004, the Company implemented steps to reduce its expenses, as a result of the unexpected termination of the GSK collaboration as well as the discontinuance of the generic clarithromycin program. The Company reduced its workforce approximately 18% and recorded a charge of \$497,049 for severance costs related to salaries and benefits, a non-cash credit of \$159,962 for the reversal of cumulative amortization of deferred stock-based compensation related to cancelled stock options, and a non-cash charge of \$49,397 for stock-based compensation related to modification of stock option agreements.

Severance and related costs incurred in connection with the workforce reductions in 2005 and 2004 were recorded as follows:

	December 31, 2005		
	Research & Development Expense	Selling, General & Administrative Expense	Total
Severance — salaries and benefits	\$2,847,220	\$1,126,045	\$3,973,265
Stock-based compensation-forfeitures	(182,581)	(329,907)	(512,488)
Accrued rent for closed office location	105,275	35,091	140,366
Total	<u>\$2,769,914</u>	<u>\$ 831,229</u>	<u>\$3,601,143</u>

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

	December 31, 2004		
	Research & Development Expense	Selling, General & Administrative Expense	Total
Severance — salaries and benefits	\$377,757	\$119,292	\$ 497,049
Stock-based compensation — forfeitures	(60,786)	(99,176)	(159,962)
Stock-based compensation — modification of options	49,397	—	49,397
Total	<u>\$366,368</u>	<u>\$ 20,116</u>	<u>\$ 386,484</u>

The following table summarizes the activity in 2005 and 2004 for the liability for the cash portion of severance costs related to the reductions-in-force:

	December 31, 2005			
	Beginning Balance	Charge	Cash Paid	Ending Balance
<u>Accrued Severance — 2005 Activity</u>				
2005 Workforce reduction	\$ —	\$3,973,265	\$ (867,392)	\$3,105,873
2004 Workforce reduction	286,515	—	(286,515)	—
	<u>\$286,515</u>	<u>\$3,973,265</u>	<u>\$(1,153,907)</u>	<u>\$3,105,873</u>
Current portion	\$286,515			\$1,870,479
Noncurrent portion	—			1,235,394
	<u>\$286,515</u>			<u>\$3,105,873</u>
	December 31, 2004			
	Beginning Balance	Charge	Cash Paid	Ending Balance
<u>Accrued Severance — 2004 Activity</u>				
2004 Workforce reduction	\$ —	\$ 497,049	\$ (210,534)	\$ 286,515

The remaining balance of \$3,105,873 at December 31, 2005 will be paid through September 2007.

Advance Payment for Potential Sale of Keflex Assets

In August 2005, Advancis entered into an agreement in principle with a private company for the potential sale of its Keflex assets, including the rights to the U.S. brand and inventories. As part of the agreement, the potential buyer made a \$1,000,000 payment to Advancis, which provided them exclusive negotiating rights through December 31, 2005. The payment was recorded as an advance, as, under certain conditions, the payment could be refundable or, if the sale were to have been completed, the \$1,000,000 payment would have been applied to the purchase price. The two parties never completed a definitive agreement for the asset sale, and in January 2006, Advancis decided to retain the brand. The agreement in principle expired on February 28, 2006. Accordingly, the advance payment of \$1,000,000 will be recognized as income in 2006.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

11. Stock-Based Compensation

The Company has recorded stock-based compensation expense for the grant of stock options to employees and to nonemployee consultants as follows:

	December 31,		
	2005	2004	2003
Employees:			
Amortization of deferred stock-based compensation . . .	\$1,522,554	\$3,296,898	\$2,181,146
Forfeitures of unvested stock options	(863,619)	(159,962)	—
Modification of options — retirement of director	—	489,951	—
Subtotal — Employees	<u>658,935</u>	<u>3,626,887</u>	<u>2,181,146</u>
Nonemployee consultants:			
Amortization of variable stock-based compensation . . .	(123,149)	26,370	549,960
Modification of options for consultant	—	—	710,157
Subtotal — Nonemployee Consultants	<u>(123,149)</u>	<u>26,370</u>	<u>1,260,117</u>
Total	<u>\$ 535,786</u>	<u>\$3,653,257</u>	<u>\$3,441,263</u>

	December 31,		
	2005	2004	2003
Included in Income Statement Captions as follows:			
Research & Development Expense	\$159,699	\$1,172,973	\$1,902,913
Selling, General and Administrative Expense	<u>376,087</u>	<u>2,480,284</u>	<u>1,538,350</u>
Total	<u>\$535,786</u>	<u>\$3,653,257</u>	<u>\$3,441,263</u>

Employees. Employee stock awards under the Company's compensation plans are accounted for by the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," (APB 25) and related interpretations. During 2003 and 2002, stock options were granted with an exercise price which was below the estimated fair market value of the common stock at the date of grant. Accordingly, deferred stock-based compensation of \$8,204,446 and \$132,940 was recorded during 2003 and 2002, respectively, and amortization of deferred stock-based compensation is charged to operations over the related vesting periods of the options. No deferred stock-based compensation was recorded in 2005 or 2004, as all options granted to employees during those years had an exercise price equal to the market value of the underlying common stock on the date of grant. Stock-based compensation expense related to employees in 2005 includes a credit of \$863,619 for the reversal of amortization upon the cancellation of forfeited options. Stock-based compensation expense related to employees in 2004 includes a charge of \$489,951 for a modification of the vesting of options incurred in connection with the retirement of the chairman of our board of directors and a credit of \$159,962 for the reversal of amortization upon the cancellation of forfeited options due to a reduction in the Company's workforce.

Non-employee Consultants. The Company has recorded stock-based compensation expense for options granted to non-employee consultants and Scientific Advisory Board (SAB) members in accordance with Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," based on the fair value of the equity instruments issued. Stock-based compensation for options granted to non-employee consultants and SAB members is periodically remeasured as the underlying options vest in accordance with Emerging Issues Task Force Issue No. 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." We recognize an expense for such options throughout the vesting period as the services are provided by the non-employee consultants and SAB members, based on the fair value of the options at each reporting period. The options are valued using the Black-Scholes option pricing model.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

The Company granted 36,000 and 178,201 stock options to non-employee consultants and Scientific Advisory Board ("SAB") members during 2005 and 2003, respectively. In 2004, no options were granted to non-employee consultants or SAB members. Except for one grant in 2003 for 85,313 options to a non-employee consultant for past services, for which the Company expensed the entire value of \$710,657 at the time of grant, the option grants required future service. As of December 31, 2005, the balance of unamortized stock-based compensation for options granted to non-employees was approximately \$50,000. This amount will be adjusted based on changes in the fair value of the options at the end of each reporting period.

12. Preferred Stock — Undesignated

On October 22, 2003, the Company's certificate of incorporation was amended to authorize the issue of up to 25,000,000 shares of undesignated preferred stock. The Company's Board of Directors, without any further action by the Company's stockholders, is authorized to issue shares of undesignated preferred stock in one of more classes or series. The Board may fix the rights, preferences and privileges of the preferred stock. The preferred stock could have voting or conversion rights that could adversely affect the voting power or other rights of common stockholders. As of December 31, 2005 and 2004, no shares of preferred stock have been issued.

13. Common Stock

Effective with the Company's initial public offering on October 22, 2003, the Company's certificate of incorporation was amended to increase the number of authorized shares of common stock to 225,000,000.

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding.

Shares Reserved for Future Issuance

The Company has 2,396,357 common shares reserved for future issuance in connection with warrants issued in the April 2005 private placement.

Reverse Stock Split

On September 5, 2003, the Company's Board of Directors authorized certain officers to complete a 1 for 1.83008 reverse stock split of common stock. On October 7, 2003, the Company's stockholders approved the reverse stock split of common stock, and the Company filed an amendment to its certificate of incorporation to complete the reverse stock split. All common share and per share amounts have been retroactively restated to reflect the reverse stock split.

Initial Public Offering

On October 16, 2003, the Company priced its initial public offering of 6,000,000 shares of common stock at an offering price of \$10.00 per share. The Company's stock started trading on October 17, 2003 on The Nasdaq National Market under the symbol "AVNC." The initial public offering was closed on October 22, 2003. The net proceeds were approximately \$54.3 million after deducting the underwriting fee and other offering expenses. Upon the closing of the initial public offering, all shares of the Company's outstanding preferred stock were automatically converted into common stock.

14. Private Placement of Common Stock

In April 2005, the Company completed a private placement of 6,846,735 shares of its common stock at a price of \$3.98 per share and warrants to purchase a total of 2,396,357 shares of common stock at an exercise price of \$4.78 per share, resulting in gross proceeds to the Company of \$27.25 million. Net proceeds to the Company after

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

deducting commissions and expenses were approximately \$25.8 million. The warrants are exercisable for five years.

Pursuant to the terms of the registration rights agreement, the Company filed with the SEC a registration statement on Form S-3 covering the resale of common stock. The registration rights agreement provides that if a registration statement is not effective within 60 days of closing, or if the Company does not subsequently maintain the effectiveness of the registration statement, then in addition to any other rights the investor may have, the Company will be required to pay the investor liquidated damages, in cash, equal to one percent per month of the aggregate purchase price paid by such investor. The SEC declared the Company's Form S-3 effective on June 1, 2005, which was within 60 days of closing.

The Company views the registration rights agreement containing the liquidated damages provision as a separate freestanding contract which has nominal value, and the Company has followed that accounting approach. The Company's view is analogous to "View C" in EITF Issue No. 05-4, *"The Effect of a Liquidated Damages Clause on a Freestanding Financial Instrument Subject to EITF Issue No. 00-19, 'Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock.'"* Under this approach, the registration rights agreement is accounted for separately from the financial instrument. Accordingly, the classification of the warrants has been determined under EITF 00-19, *"Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock,"* and the warrants have been accounted for as permanent equity.

The Company has valued the liquidated damages provision of the registration rights agreement at nominal value. In determining this as the fair value, the Company considered the following factors. The agreement provides that there is a 60-day period to have the registration statement declared effective before liquidated damages apply. The Company believed at the closing of the private placement that it was probable the registration statement would be declared effective within the 60-day period. The registration statement was declared effective in less than 60 days and in the same fiscal quarter as the closing of the private placement, and therefore the Company was aware that there was no value to the liquidated damages provision for the initial 60 day period. The liquidated damages provision would only have value in the future if the S-3 registration statement became ineffective in a future period for more than 45 days in any 12-month period. The Company believes the events that would lead to a suspension of effectiveness are unlikely to occur. In future periods, should the Company conclude that it is probable, as defined in SFAS No. 5, *"Accounting for Contingencies,"* that a liability for liquidated damages will occur, the Company will record the estimated cash value of the liquidated damages liability at that time.

15. Beneficial Conversion Features

Beneficial Conversion Feature — Interest Expense on Convertible Notes

On March 28, 2003, the Company issued \$5.0 million of convertible notes to certain of its existing preferred stockholders. In July 2003, the note holders exercised their right to convert the convertible notes and accrued interest into 2,263,272 shares of the Company's Series E mandatorily redeemable convertible preferred stock. The Series E preferred stock was convertible into common stock at a price per share which was below the estimated fair value of the Company's common stock at the date of issuance of the notes. Accordingly, the Company recorded a "non-cash beneficial conversion charge" of \$1.7 million as additional interest expense for the year ended December 31, 2003.

Beneficial Conversion Feature- Series E Mandatorily Redeemable Convertible Preferred Stock

In July 2003, the Company completed the sale of 9,292,284 shares of Series E mandatorily redeemable convertible preferred stock for proceeds of \$20.9 million. After evaluating the fair value of the Company's common stock in contemplation of its initial public offering, the Company determined that the issuance of the Series E preferred stock resulted in a beneficial conversion feature calculated in accordance with EITF Issue No. 00-27,

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

"Application of Issue No. 98-5 to Certain Convertible Instruments" of \$20.9 million which was accreted in July 2003 and is reflected in the net loss applicable to common stockholders for the year ended December 31, 2003.

16. Stock Option Plan

The Company currently grants stock options under the Stock Incentive Plan (the "Plan"). In May 2005, the number of shares available for issuance under the Plan was increased by 1,500,000 to 7,848,182.

Options granted under the Plan may be incentive stock options or non-statutory stock options. Stock purchase rights may also be granted under the Plan. Incentive stock options may only be granted to employees. The compensation committee of the Board of Directors determines the period over which options become exercisable. Options granted to employees, consultants and advisors normally vest over a 4-year period. Options granted to directors, upon their initial appointment or election, vest monthly over periods of 36 or 48 months. Annual director grants vest monthly over 12 months. The exercise price of incentive stock options and non-statutory stock options shall be no less than 100% of the fair market value per share of the Company's common stock on the grant date. The term of all options is 10 years except, with respect to one incentive stock option held by a Company executive, the term of which is 5 years. As of December 31, 2005 and 2004, there were 2,598,019 and 1,627,865 shares of common stock available for future option grants, respectively.

The following table summarizes the activity of the Company's stock option plan for the years ended December 31, 2005, 2004 and 2003:

	<u>Number of Options</u>	<u>Weighted- Average Exercise Price</u>
Outstanding, December 31, 2002	844,198	\$0.53
Granted	1,741,057	4.30
Exercised	(306,446)	0.91
Cancelled	<u>(43,321)</u>	<u>1.32</u>
Outstanding, December 31, 2003	2,235,488	3.45
Granted	1,660,550	8.00
Exercised	(26,764)	0.61
Cancelled	<u>(132,548)</u>	<u>5.15</u>
Outstanding, December 31, 2004	3,736,726	5.43
Granted	1,926,350	3.24
Exercised	(171,155)	0.59
Cancelled	<u>(1,396,504)</u>	<u>4.89</u>
Outstanding, December 31, 2005	<u><u>4,095,417</u></u>	<u><u>\$4.79</u></u>

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

The following table summarizes information about stock options outstanding, and exercisable at December 31, 2005:

Range of Exercise Prices	Number Outstanding	Options Outstanding		Options Exercisable	
		Weighted- Average Remaining Contractual Life	Weighted -Average Exercise Price	Number Exercisable	Weighted -Average Exercise Price
December 31, 2005					
\$0.28 to \$0.62	829,853	5.9	\$0.56	678,820	\$0.55
\$0.93 to \$1.41	800,201	9.0	1.18	204,282	1.32
\$2.81 to \$4.80	873,991	9.1	4.19	349,006	4.27
\$8.40 to \$10.00	<u>1,591,372</u>	<u>8.1</u>	<u>9.14</u>	<u>1,053,324</u>	<u>9.19</u>
	4,095,417	8.0	\$4.79	2,285,432	\$5.17

Restricted Stock

Certain of the Company's directors, consultants and employees (and/or immediate family members or related entities to which certain of those individuals have transferred their options or shares of common stock) have entered into the Company's standard form of stock restriction agreement as a condition to their exercise of options to acquire common stock pursuant to the Plan. These agreements provide, among other things, for a right of first refusal to the Company in connection with the option holder's sale of the common stock, as well as the right for the Company to purchase the stockholder's common stock in the event that the stockholder's relationship with the Company is terminated under certain circumstances. Shares issued under non-statutory stock options exercised prior to vesting are subject to forfeiture in accordance with the vesting schedule of the granted stock options. During 2003, certain of the Company's employees, board members and consultants exercised unvested stock options, awarded under the Company's Stock Incentive Plan, to acquire a total of 139,332 shares of restricted common stock. There were no such exercises in 2004 or 2005. At December 31, 2005 and 2004, 71,032 and 237,689 shares, respectively, of restricted common stock remain unvested pursuant to awards.

Consistent with the provisions of EITF No. 00-23, "Issues Related to the Accounting for Stock Compensation under APB Opinion No. 25 and FASB Interpretation No. 44," for all exercises of stock options into unvested restricted stock after March 2002, the Company recorded a liability for the amount of the proceeds received, which is reclassified to equity upon the vesting of the restricted stock. As of December 31, 2005 and 2004, \$42,770 and \$67,480 related to 68,983 and 109,553 shares of restricted stock, respectively, were recorded as a liability.

Of the stock options exercised in 2001 into unvested restricted stock, Dr. Rudnic and two affiliated trusts exercised a total of 295,069 non-statutory stock options in October 2001. The exercise price was paid through the issuance of full-recourse promissory notes in the aggregate principal amount of \$121,500. Interest accrues on the notes at 5.50% and the term of the notes is five years. The shares issued upon exercise of the options were pledged as security for the repayment of the promissory notes (the "Pledge"). In addition, pursuant to the terms of a stock restriction agreement, all of these shares were subject to repurchase by the Company upon any termination of Dr. Rudnic's employment (the "Termination Repurchase Right"). In February 2002, the stock restriction agreement was amended to provide the Company with an additional right, upon the Company's request, to repurchase 54,642 of the shares from Dr. Rudnic if the Company failed to meet certain performance milestones during 2002 (the "Milestone Repurchase Right"). In January 2003, the Company's Board of Directors decided not to exercise the Company's Milestone Repurchase Right. The Milestone Repurchase Right was never exercised by the Company and lapsed in February 2003. The 54,642 shares remain subject to the Pledge and the Termination Repurchase Right.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

17. Income Taxes

The Company has not recorded any tax provision or benefit for the years ended December 31, 2005, 2004 and 2003. The Company has provided a valuation allowance for the full amount of its net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carryforwards cannot be sufficiently assured at December 31, 2005 and 2004.

Deferred tax assets consist of the following:

	<u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
Net operating loss carryforwards	\$ 31,161,022	\$ 20,053,953
Start-up costs	1,666,653	2,262,998
Deferred revenue	4,629,075	3,635,481
Depreciation and amortization	19,269	(57,645)
Stock-based compensation	2,742,775	2,511,904
Advance payment for potential sale of Keflex brand rights	398,200	—
Accrued severance	1,236,789	110,652
Other accrued expenses and other items	847,868	359,245
Patent costs	387,520	284,816
Research and experimentation tax credit	4,941,432	2,709,109
Deferred tax assets	48,030,603	31,870,513
Valuation allowance	(48,030,603)	(31,870,513)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The effective tax rate differs from the U.S. federal statutory tax rate of 34% due to the following:

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
U.S. federal statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal tax benefit	(5.8)%	(4.6)%	(4.1)%
Beneficial conversion feature — deemed interest expense	—	—	2.7%
Permanent items	0.2%	0.4%	0.7%
Research and experimentation tax credit	(6.3)%	(4.2)%	(2.1)%
Change in valuation allowance	45.9%	42.4%	36.8%
Effective tax rate	<u>(0.0)%</u>	<u>(0.0)%</u>	<u>(0.0)%</u>

At December 31, 2005 and 2004, the Company had federal and state net operating loss carryforwards of approximately \$78.3 million and \$51.9 million, respectively, available to reduce future taxable income, which will begin to expire in 2020. At December 31, 2005, the Company had federal research and experimentation tax credit carryforwards of approximately \$4.6 million which begin to expire in 2020 and state tax credit carryforwards of \$0.3 million which begin to expire in 2018.

Under the provisions of Section 382 of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss and research and experimentation tax credit carryforwards which can be utilized in future years. During 2005 and prior years, the Company may have experienced such ownership changes. When the Company completes the necessary studies, the amount of net operating loss carryovers may be reduced. However, since the valuation allowance fully reserves for all available

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

carryovers, the effect of the reduction would be offset by a reduction in the valuation allowance. Thus, the resolution of this matter would have no effect on the reported assets, liabilities, revenues and expenses for the periods presented.

18. 401(k) Savings Plan and Employee Stock Purchase Plan

During 2000, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company's Board of Directors has discretion to match contributions made by the Company's employees. To date, no matching contributions have been made by the Company.

During 2003, the Company adopted an employee stock purchase plan which provides for the issuance of up to 100,000 shares of common stock. This plan, which is intended to qualify under Section 423 of the Internal Revenue Code, provides the Company's employees with an opportunity to purchase shares of its common stock through payroll deductions. Options to purchase the common stock may be granted to each eligible employee periodically. The purchase price of each share of common stock will not be less than the lesser of 85% of the fair market value of the common stock at the beginning or end of the option period. Participation is limited so that the right to purchase stock under the purchase plan does not accrue at a rate which exceeds \$25,000 of the fair market value of our common stock in any calendar year. To date, no shares have been issued under this plan.

19. Commitments and Contingencies

Leases

In August 2002, the Company entered into a 10-year lease for its corporate, research and development facility in Germantown, Maryland, which is renewable for two periods of five consecutive years each at the end of the original term. The Company took possession of the lease space during 2003. In conjunction with the execution of the lease agreement, the Company provided the landlord with a letter of credit, which the Company collateralized with a restricted cash deposit in the amount of \$753,000 at December 31, 2005 and 2004 (see Note 2). The lease includes scheduled base rent increases over the term of the lease. The total amount of the base rent payments will be charged to expense on the straight-line method over the term of the lease (excluding renewal periods). In 2004 and 2003, the Company received \$87,078 and \$830,010, respectively, in cash from the landlord in connection with the build-out of the facility. These amounts were recorded as deferred rent and are being amortized on a straight-line basis as a reduction to rent expense over the term of the lease.

In August 2004, the Company leased additional space adjacent to its Germantown, Maryland, facility. This lease, which includes a rent holiday and scheduled rent increases annually over its term, is being charged to expense on a straight-line basis over the entire term of the lease, which expires May 31, 2013. In conjunction with the execution of the lease agreement, the Company provided the landlord with a letter of credit, which the Company collateralized with a restricted cash deposit in the amount of \$306,000 at December 31, 2005 and 2004. (see Note 2).

The Company also leased additional laboratory space in Gaithersburg, Maryland, under a lease which expired in November 2005, and office space in New Jersey under a lease which expires in September 2006. The Company also leases office equipment expiring at various dates through 2008.

Rent expense under all leases, including deferred rent adjustments as well as the accrual of the remaining rent of \$140,366 for the New Jersey office closed in 2005, was \$2,472,819, \$1,599,662, and \$671,537 for the years ended December 31, 2005, 2004 and 2003, respectively.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

Future minimum lease payments under noncancelable operating leases at December 31, 2005 are as follows:

<u>Year Ending December 31,</u>	<u>Operating Leases</u>
2006	\$ 2,125,808
2007	2,079,474
2008	2,139,250
2009	2,156,210
2010	2,214,399
Thereafter	<u>5,318,359</u>
Total	<u>\$16,033,500</u>

Royalties

In the event the Company is able to develop and commercialize a PULSYS-based Keflex product, another cephalixin product relying on the acquired NDAs, or other pharmaceutical products using the acquired trademarks, Eli Lilly will be entitled to royalties on these new products. Royalties are payable on a new product by new product basis for five years following the first commercial sale for each new product, up to a maximum aggregate royalty per calendar year. All royalty obligations with respect to any defined new product cease after the fifteenth anniversary of the first commercial sale of the first defined new product.

Legal Proceedings

The Company is a party to legal proceedings and claims that arise during the ordinary course of business. In December 2003, Aventis and Aventis Pharmaceuticals Inc., now part of sanofi-aventis, brought an action against the Company in the U.S. District Court for the District of Delaware. The Complaint contains six counts, based upon both federal and state law, alleging, in essence, that the Company has infringed on the plaintiffs' trademark. The plaintiffs seek injunctive relief, as well as unspecified monetary damages. Discovery has been completed, the trial was held in May 2005, and the Company is currently waiting for the judgment of the Court. It is the opinion of management that the ultimate outcome of this matter will not have a material adverse effect upon the Company's financial position but could possibly have a material adverse effect on its results of operations for a particular period.

20. Related Party Transactions

Loans to Executive Officer

In October 2001, the Company provided loans to Dr. Edward Rudnic, our president, chief executive officer and a director, and two trusts affiliated with Dr. Rudnic, that are evidenced by full recourse notes in the aggregate principal amount of \$121,500. The notes bear interest at a fixed annual interest rate of 5.5%, with the interest payable annually, and mature in October 2006. The proceeds from these notes were used to exercise options to purchase 295,069 shares of our common stock (see Note 16). The loans are secured by 295,069 shares of our common stock issued to Dr. Rudnic and the two trusts, plus any additional shares purchased by these holders. Following exercise, Dr. Rudnic transferred by gift a total of 38,250 shares of our common stock to five family members and two other individuals. The shares of common stock remain pledged to secure the loans to Dr. Rudnic. As of both December 31, 2005 and 2004, the total amount outstanding under the loans was \$123,171, including accrued interest which is paid annually.

ADVANCIS PHARMACEUTICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

Consulting Arrangements

In December 2002, the Company entered into a consulting arrangement with Mr. James D. Isbister, the chairman of our board of directors, which provides for a payment to Mr. Isbister of \$60,000 per year in exchange for consulting services. These consulting services include tactical advice and planning with regard to corporate operations, financing approaches, and product development and commercialization strategies.

Effective May 1, 2004, Mr. James D. Isbister retired as the chairman of the board of directors. At that time, the Company entered into a new agreement with Mr. Isbister which provides for a payment to him of up to \$100,000 per year in exchange for consulting services. The initial term of the agreement is for 40 months, and it may be renewed by mutual agreement.

Also on May 1, 2004, Mr. Isbister and the Company entered into an agreement to amend the stock option agreements with Mr. Isbister, to provide for the continued vesting of unvested restricted stock and for accelerated vesting in the event of a termination by the Company of the consulting agreement with Mr. Isbister or a defined change in control of the Company. As a result of his change in status from director to consultant and the Company waiving its right to repurchase the restricted stock issued for options which had been early exercised by Mr. Isbister, the Company recorded a stock-based compensation charge of \$489,951.

In December 2002, the Company entered into a consulting agreement with Jenefir D. Isbister, Ph.D., the spouse of Mr. James Isbister and a professor and research microbiologist at George Mason University. Under the terms of the consulting agreement, the Company pays Dr. Isbister \$1,500 per day for consultation and research support services in connection with our identification and development of pulsatile antibiotic delivery strategies. Due to the retirement of her husband from the Board of Directors on May 1, 2004, Dr. Isbister is no longer a related party. In 2004 (through May, 2004) and 2003, the Company paid an aggregate of \$28,000 and \$56,000, respectively, to Dr. Isbister under this agreement. The Company also granted options in 2003 to Dr. Isbister that were exercised for 43,714 shares of our common stock at a weighted average exercise price of \$0.53 per share.

21. Quarterly Financial Data (Unaudited)

The following table presents unaudited quarterly financial data of the Company. The Company's quarterly results of operations for these periods are not necessarily indicative of future results of operations.

	<u>Revenue</u>	<u>Operating Loss</u>	<u>Net Loss</u>	<u>Net Loss Applicable to Common Stockholders</u>	<u>Basic and Diluted Net Loss Per Share Applicable to Common Stockholders</u>
Year ended					
December 31, 2005					
First quarter	\$4,626,656	\$(11,518,582)	\$(11,388,603)	\$(11,388,603)	\$(0.50)
Second quarter	3,200,839	(9,555,757)	(9,312,832)	(9,312,832)	(0.34)
Third quarter	7,401,313	(6,169,988)	(5,880,240)	(5,880,240)	(0.20)
Fourth quarter	1,618,882	(6,714,736)	(6,406,902)	(6,406,902)	(0.22)
Year ended					
December 31, 2004					
First quarter	\$ 312,500	\$(10,810,926)	\$(10,620,800)	\$(10,620,800)	\$(0.47)
Second quarter	854,454	(8,646,781)	(8,490,152)	(8,490,152)	(0.37)
Third quarter	3,073,740	(9,405,491)	(9,228,081)	(9,228,081)	(0.41)
Fourth quarter	7,117,338	(5,810,963)	(5,665,680)	(5,665,680)	(0.25)

SCHEDULE II

ADVANCIS PHARMACEUTICAL CORPORATION

VALUATION AND QUALIFYING ACCOUNTS

Years Ended December 31, 2005, 2004, and 2003

	<u>Balance at Beginning of Period</u>	<u>Additions</u>	<u>Deductions(1)</u>	<u>Balance at End of Period</u>
Accounts receivable allowances:				
Year Ended December 31, 2005	\$ 128,569	\$ 690,463	\$(466,112)	\$ 352,920
Year Ended December 31, 2004	\$ —	\$ 200,553	\$ (71,984)	\$ 128,569
Year Ended December 31, 2003	\$ —	\$ —	\$ —	\$ —
Inventory reserves:				
Year Ended December 31, 2005	\$ —	\$ 154,367	\$ —	\$ 154,367
Year Ended December 31, 2004	\$ —	\$ —	\$ —	\$ —
Year Ended December 31, 2003	\$ —	\$ —	\$ —	\$ —
Deferred tax asset valuation reserves:				
Year Ended December 31, 2005	\$31,870,513	\$16,160,090	\$ —	\$48,030,603
Year Ended December 31, 2004	\$17,448,221	\$14,422,292	\$ —	\$31,870,513
Year Ended December 31, 2003	\$ 9,716,217	\$ 7,732,004	\$ —	\$17,448,221

- (1) Deductions represent utilization of the allowances. For accounts receivable, these include the deduction by customers of prompt pay discounts from their payments, chargebacks made by wholesalers to the Company, and writeoffs of bad debts, if any.

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Corporate Information

Management

Edward M. Rudnic, Ph.D.
President & Chief Executive Officer

Robert C. Low
Vice President, Finance & Acting Chief Financial Officer

James Bruno
Vice President, Pharmaceutical Sales

Darren W. Buchwald
*Vice President, Commercial Development,
Sales & Marketing*

Beth A. Burnside, Ph.D.
Vice President, Pharmaceutical Research

Susan P. Clausen, Ph.D.
*Vice President, Clinical Research
& Regulatory Affairs*

Donald J. Treacy, Ph.D.
*Vice President, Analysis
& Pharmaceutical Quality*

Sandra E. Wassink
*Vice President, Pharmaceutical
Development Operations*

Board of Directors

R. Gordon Douglas, M.D. (Chairman)
*Consultant, Vaccine Research Center
at the National Institutes of Health
Former President, Merck Vaccines*

Edward M. Rudnic, Ph.D.
*Founder, President and Chief Executive Officer,
Advancis Pharmaceutical Corp.*

James H. Cavanaugh, Ph.D.
General Partner, HealthCare Ventures LLC

Richard W. Dugan
Former Partner, Ernst & Young LLP

Wayne T. Hockmeyer, Ph.D.
Founder and Chairman, MedImmune, Inc.

Harold B. Werner
General Partner, HealthCare Ventures LLC

Wm. William McCormick Blair, Jr. (Senior Advisor)
Director Emeritus, Albert and Mary Lasker Foundation



Corporate Headquarters

20425 Seneca Meadows Parkway
Germantown, MD 20876
301 944-6600 • www.advancispharm.com

Transfer Agent

Questions concerning lost stock certificates, address changes, stock transfers or other stockholder matters should be directed to: American Stock Transfer & Trust Company
59 Maiden Lane, New York, NY 10038
800 937-5449 • www.amstock.com

Form 10-K

Copies of the Company's Form 10-K filed with the Securities and Exchange Commission along with other corporate information are available upon request by contacting the Company at: 20425 Seneca Meadows Parkway, Germantown, MD 20876
Attention: Investor Relations
301 944-6600

Annual Meeting

Advancis Pharmaceutical's annual meeting of stockholders will take place on May 24, 2008, at 8:30 a.m. in the main boardroom of the Company's corporate headquarters in Germantown, Maryland.

Corporate Advisors

Ernst & Young
250 West Pratt Street, Suite 2100, Baltimore, MD 21201
410 788-7600

Legal Counsel

Dewey Ballantine LLP
1301 Avenue of the Americas, New York, NY 10019
212 260-8000

Trademarks

Advancis, Advancis Pharmaceutical, Adv, The Advancis logo, P.D. SYS and Keflex are trademarks and service marks of Advancis Pharmaceutical Corp. Other trademarks, trade names or service marks referred to are the property of their respective owners.

Common Stock Data

The Company's common stock has traded on the NASDAQ National Market under the symbol AVNC since the Company's initial public offering on January 17, 2008. As of March 31, 2009, the Company had 132 shareholders of record, 100,000,000 shares of common stock outstanding and 3,290,582 shares of common stock reserved for issuance.

For additional information, including information about Advancis Pharmaceutical's annual report, please visit www.advancispharm.com.



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